BON SECOURS COLLEGE FOR WOMEN (AUTONOMOUS)

Nationally Accredited with 'A++' Grade by NAAC in Cycle II
Affiliated to Bharathidasan University, Tiruchirappalli
UGC Recognized 2(f) and 12(B) Institution
Vilar Bypass, Thanjavur – 613006, Tamil Nadu

M.Sc., Biotechnology
SEMESTER I

Core Theory I: 24PBT101 - ADVANCES IN CELL AND MOLECULAR BIOLOGY

Contact Hours/Week: 04 Credits: 04
Internal Mark: 25 External Mark: 75
Course Outcomes:

UNIT	CO. No.	UPON COMPLETION OF THIS COURSE THE STUDENTS WILL BE ABLE TO	COGNITIVE LEVEL
Unit-I	**CO1**	Understand the cell organelles cytoskeleton and Transport system	K1 –K3
Unit-II	**CO2**	Understand the Cell Communications	K1 – K3
Unit-III	**CO3**	Acquire knowledge of Genome Regulation.	K1 –K3
Unit-IV	**CO4**	Describe the regulation of gene and repair mechanism	K1 – K4
Unit-V	**CO5**	Analyze the molecular tools in the phylogeny of gene sequences.	K1 – K5

K1- Remember; **K2** – Understand; **K3** – Apply; **K4**- Analyze; **K5**- Evaluate; **K6**- Create

SYLLABUS

Unit I - Cell Architecture

Cell Organization- Cell organelles and functions. Cytoskeleton of Cell Organelles, Membrane structure and function: Structure of model membrane; ion channels; ion pumps; active transport; mechanism of sorting and regulation of intracellular transport; electrical properties of membrane. Membrane Transport - Passive and facilitated diffusion, active transport, symport, antiport, ATPase, ion channels, Aquaporins. Signal transduction pathway, types of Signalling, Messengers

Unit II: Cell Communication

Introduction, signaling molecules and receptors; an overview of different signaling pathways. Cellular transport: Brief outline of protein targeting to Mitochondria, Chloroplast, Endoplasmic reticulum and Nuclear transport; Protein modifications, Folding, Vesicular transport, Secretion, Endocytosis. Cell division: Different phases of

Cell cycle; MPF; Checkpoints in Yeast and Mammalian cell cycle; Stem cells- properties; Programmed Cell Death.

Unit III: Genome organization

Organization of genomes in prokaryotes and eukaryotes, Chromatin organization and packaging; DNA reassociation kinetics (Cot curve analysis); Repetitive and unique sequences; Satellite DNA; DNA melting and buoyant density; Nucleosome phasing; DNase I hypersensitive regions; DNA methylation, Telomeres and telomerase, DNA topology, Knots and links, Linking number, Writhing and twisting, DNA supercoiling, Topoisomers, Role of DNA topology in replication and transcription. DNA Topoisomerases in prokaryotes and eukaryotes.

Unit IV: Gene regulation

Regulation of gene expression in prokaryotes and Eukaryotes, Operon Model, Attenuation, Antitermination and Chi sequences in prokaryotes; Gene targeting; Gene disruption; FLP/FRT and Cre/Lox recombination, different kinds of DNA damage, DNA repair mechanisms in prokaryotes and eukaryotes, Diseases due to failure of DNA repair –Xeroderma Pigmentosum (XP), Hereditary Nonpolyposis Colorectal Cancer (HNPCC), Ataxia Telangiectasia (AT), Bloom Syndrome

Unit V: MolecularEvolution:

Concepts of evolution, molecular divergence and molecular clocks; molecular tools in phylogeny, classification and identification; protein and nucleotide sequence analysis; origin of new genes and proteins; gene duplication and divergence, Speciation; allopatric and sympatric; convergent evolution; sexual selection; co-evolution

Text Books:

- Unit -1 –Lennan A. G, Bates A. D & White M.R.H, Turner P.C,(2007),.*Molecular Biology*-Bios Scientific Pub Ltd;
- Unit -2 -Peter Snustad D., Michael J, Simmons, (2012) ,*Principles of Genetics-6th edition*, John Wiley and Sons.
- Unit -3 - Lodish, Baltimore *et al*.,(2007). *Molecular Biology,6thEdn,* W. H. Freeman & Co
- Unit- 4 – Benjamin A, Pierce, Robert Schleif (1996). *Genetics &MolecularBiology-2ndedition,* Uttarakhand open university.
- Unit -5 –Watson, Pearson,J. D. *et al.,*(2017), *Molecular Biology of Gene, 7th edition*, Pearson Education.

Core Theory II: 24PBT102 - ADVANCES IN MICROBIOLOGY

Contact Hours/Week: 04 **Credits: 04**

Internal Mark: 25 **External Mark: 75**

Course Outcomes:

UNIT	CO. No.	Upon completion of this course the students will be able to	COGNITIVE LEVEL
Unit-I	**CO1**	Acquiring Knowledge on Introduction of Microbiology and microbes	K1 – K3
Unit-II	**CO2**	Understand the Metabolic diversity and Extremophiles	K1 – K3
Unit-III	**CO3**	Optimize the Microbial growth.	K1 – K4
Unit-IV	**CO4**	Analyze the Host Microbes Relationships.	K1 - K5
Unit-V	**CO5**	Apply the Genomics studies on Microorganisms	K1 - K6

K1- Remember; **K2** – Understand; **K3** – Apply; **K4**- Analyze; **K5**- Evaluate; **K6**- Create

SYLLABUS

Unit I: Introduction of microbiology and microbes

Applications of Microbiology in various fields- Industries, Food, Agriculture, Environment, Medical and Research. Principles of -microbial nutrition; Construction of culture media; Enrichment culture techniques for isolation of nutritional categories. Culture collection and maintenance of cultures.

Unit II: Metabolic diversity and Extremophiles:

Autotrophy; Chemolithotrophs; Nitrogen Metabolism and Fixation, Methanogenesis and acetogenesis; Microbial Diversity: Bacteria: Purple and green bacteria, cyanobacteria, acetic acid bacteria, Extremophiles, Thermophiles, Psychrophiles, Acidophiles, Alkaliphiles, Halophiles, Basophiles, Piezophiles, archaea; Thermoplasma. Eukarya: Algae, Fungi, Slime mold sand Protozoa.

Unit III: Microbial Growth:

Growth phases: Measurement, Mean Generation time, Factors affecting growth. Effect of temperature, pH, osmotic pressure, hydrostatic pressure and radiation on microbial growth. Synchronous, culture. Kinetics of microbial growth; Batch culture, continuous culture, types of continuous culture, system- turbidostat, chemostat. Microbial biofilms and quorum sensing, Microbial interactions in microbial communities.

Unit IV: Host Microbes Relationships:

Normal microflora of skin, oral cavity, Gastrointestinal tract; Entry of pathogens into the host; colonization and factors predisposing to infections; types of toxins and their structure; Modeo factions; Virulence and Pathogenesis. Chemotherapy/Antibiotics: Antimicrobial agents; Sulfa drugs; Antibiotics: Penicillin and Cephalosporins; Broad-

spectrum antibiotics; Antibiotics from prokaryotes; Antifungal antibiotics; Mode of action; Resistance to antibiotics. Plant – Host Interactions.

Unit V: Microbial Genomics:

Introduction; Characteristics of Microbial Genomes–Importance of microbial functional genomics of Prokaryotes and Eukaryotes. Genomic diversity within the species; Genome annotation. Methods of genome analysis: Types of gene map: Genetic and physical and restriction site mapping. Genomic finger printing. Genome sequencing: high throughput sequencing, next generation DNA sequencing technologies.

Text Books:

- Unit -1 - Bauman, R.W, (2009). *Microbiology, 2nd edition*, Pearson Benjamin Cummings.
- Unit -2- Prescott, Prescott. L.M, Harley and Klein's, (2007). *Microbiology., 6th Edition* McGraw-Hill education.
- Unit -3- Tortora GJ, Funke B.R, Case CL. (2004*). Microbiology: An introduction, 8th Edition* SanFrancisco: Pearson,
- Unit -4 -Joan L. Slonczewski and John W. Foster. W.W. (2017), *Microbiology*, W W Norton & Co Inc;
- Unit -5 -Hans G. Schlegel (Germany), (1993*), "General Microbiology", 7th Edition* Cambridge University Press.

Core Theory III: 24PBT103 - ADVANCES IN BIOCHEMISTRY

Contact Hours/Week: 04 **Credits: 04**

Internal Mark: 25 **External Mark: 75**

Course Outcomes:

UNIT	CO. No.	UPON COMPLETION OF THIS COURSE THE STUDENTS WILL BE ABLE TO	COGNITIVE LEVEL
Unit-I	**CO1**	Understand the bioenergetics	K1 – K3
Unit-II	**CO2**	Understand the Law of Thermodynamics and metabolism	K1 – K3
Unit-III	**CO3**	Apply the Carbohydrate and Lipids process.	K1 – K4
Unit-IV	**CO4**	Analyse Proteins and Amino acids Metabolism	K1 – K5
Unit-V	**CO5**	Apply the regulatory frameworks of Metabolism	K1 – K5

K1- Remember **K2** – Understand **K3** – Apply **K4**- Analyze **K5**- Evaluate **K6**- Create

SYLLABUS

Unit I: Bioenergetics:

Free energy and entropy. Phosphoryl group transfers and ATP. Enzymes involved in redox reactions. The electron transport chain–organization and role in electron capture. Electron transfer reactions in mitochondria. Oxidative phosphorylation- F1/F0 ATPase - structure and mechanism of action. The chemiosmotic theory. Inhibitors of respiratorychain and Oxidative phosphorylation – uncouplers, ionophores. Regulation of oxidative phosphorylation.

Unit II: Law Of Thermodynamics:

Basic principles, equilibrium and concept of free energy, redox potential and their applications. Coupled processes - process of photosynthesis. Logic and integration of central metabolism – entry and exit of various biomolecules from central pathways. Principles of metabolic regulation. Regulatory steps, signals and secondary messengers.

Unit III: Carbohydrates and Lipids:

Carbohydrates Structure and classification. Sugars - mono, di, and polysaccharides, chemical composition and bonding. Cellular structure, energy storage and signaling. Glycosylation of biomolecules – glycoproteins and glycolipids. Glycolysis, Kreb'scycle, Gluconeogenesis and HMP pathway. CSDB (Carbohydrate Structure Database, Glycome DB, Calvin cycle). Lipids - Structure, classification and properties. Lipid metabolism. Oxidation - Fatty acids and cholesterol. Biosynthesis of lipids. Lipid storage and membrane lipids. Lipoproteins. Bio membrane organization - sidedness and 8 function. Membrane bound proteins - structure, properties and function. Transport phenomena of nucleosides and nucleotides.

Unit IV: Amino Acids, Proteins and Enzymes- Amino acids:

Structure and functional group, properties. Biosynthesis, types, metabolism. Proteins - Peptides and covalent structure of proteins. Elucidation of primary and higher order structures. structural characteristics of protein. Structure - function relationship in model proteins like ribonuclease A, myoglobin, hemoglobin and chymotrypsin. Tools to characterize the expressed proteins. Enzymes - Nomenclature, classification, properties, structure and functional relationship. Quantification of enzyme activity and efficiency. Enzyme characterization and Michaelis-Menten kinetics. Relevance of enzymes in metabolic regulation, activation, inhibition and covalent modification. Single substrate and multi substrate enzymes. Mechanism of action.

Unit V: Metabolism Of Purines and Pyrimidines:

Digestion and absorption of nucleoproteins, Fractionation, sequencing and chemical synthesis of oligonucleotides. Metabolism of purines-de novo and salvage pathways for purine biosynthesis, regulation of biosynthesis of nucleotides. Purine catabolic pathway. Metabolism of pyrimidines - biosynthesis and catabolism. Disorders of purine and pyrimidine metabolism, intermediary metabolism and KEGG pathway.

Texts Books:

- Unit-1- Lehninger. L (2004). *Principles of Biochemistry, 4th Edition*. W.H Freeman and Company.
- Unit-2 -Stryer. (2002). *Biochemistry. 5th Edition*. W.H. Freeman and Company.
- Unit -3 - Chattergea Rana Shinde. M.N (2011). *Text book of Medical Biochemistry. 8th Edition.* J.P. Medical Ltd.
- Unit- 4- Donald Voet and Judith G. Voet. (2004). *Biochemistry. 3rd Edition*, John Wiley, New York.
- Unit-5 - Allan Fershi. (1984*). Enzyme structure and mechanism. 2nd Edition,* W.H. Freeman & Co. Ltd.,USA.

Core Laboratory - I: 24PBT301 - ADVANCES IN CELL AND MOLECULAR BIOLOGY PRACTICAL

Contact Hours/Week: 04 **Credits: 04**
Internal Mark: 40 **External Mark: 60**

Course Outcomes:

CO. No.	Upon completion of this course the students will be able to	Cognitive Level
CO1	Observe the Cell divisions.	K1 - K4
CO2	Isolate and quantify the Nucleic acids	K1 - K4
CO3	Amplify the DNA	K1 - K4
CO4	Analyse the Mutagenesis of DNA	K1 - K5
CO5	Observe the Genetic Transformation.	K1 - K6

K1- Remember **K2** – Understand **K3** – Apply **K4**- Analyze **K5**- Evaluate **K6**- Create

SYLLABUS

1. Laboratory safety and Good laboratory Practices (GLP)
2. Preparation of different stock solutions used in cell and molecular biology (Solutions used in electrophoresis, DNA isolation, RNA isolation and Protein isolation etc.)
3. Cell count - prokaryotic & eukaryotic.
4. Giant chromosome studies in Chironomous larvae.
5. Squash preparation for chromosome staining for mitosis (Onion root tip).
6. Visualization of Meiosis stages (Grasshopper Testes and *Vicia faba*).
7. Temporary and permanent slide preparation.
8. Sub-cellular fractionation.
9. Isolation and purification of genomic DNA from prokaryotes.
10. Isolation and purification of genomic DNA from eukaryotes.
11. Isolation and purification of plasmid DNA.
12. Observation of DNA - Agarose gel electrophoresis
13. Quantification of Nucleic Acids – DNA & RNA – Chemical method.
14. Separation of protein by SDS PAGE and Protein staining techniques. Amido black, Coomassie brilliant blue & AgNO3.
15. Amplification of DNA - PCR
16. Bacterial mutagenesis – Physical & Chemical (Ames Test)
17. Preparation of *E. coli* competent cells
18. Transformation of bacteria – CaCl2 method.
19. Bacterial Conjugation.
20. Transduction.
21. ELISA Technique – Demonstration

TEXT BOOKS:

- Emanuel Goldman, Lorrence H. (2009), Green Practical Hand Book of Microbiology, *CRC Press*
- K.R. Aneja, (2014), Laboratory manual of Microbiology and Biotechnology, *Standard Edition*
- D.R., Arora (2007), Practical Microbiology Bharti Arora, *CBS Publishers & Distributors.*
- S. Rajan (2019). Experimental procedure in Life Sciences. *CSB Publishers.*

Core Laboratory - II: 24PBT302 - ADVANCES IN MICROBIOLOGY AND BIOCHEMISTRY PRACTICAL

Contact Hours/Week: 04 **Credits: 04**
Internal Mark: 40 **External Mark: 60**

CO. No.	UPON COMPLETION OF THIS COURSE THE STUDENTS WILL BE ABLE TO	COGNITIVE LEVEL
CO1	Isolate and Quantify the Biomolecules	K1 - K4
CO2	Isolate the Microorganisms from various sources	K1 - K4
CO3	Analyse the Microbial Growth Curve with environmental factor	K1 - K4
CO4	Analyse the Antibiotic Susceptibility of Microorganisms	K1 - K5
CO5	Isolate the Bacteriophage	K1 - K6

Course Outcomes:

K1- Remember **K2** – Understand **K3** – Apply **K4**- Analyze **K5**- Evaluate **K6**- Create

SYLLABUS

1. Preparation of Acetate and phosphate buffer system and validate the Henderson Hasselbach equation.
2. To determine concentration of an unknown protein by UV-Vis Spectrophotometer.
3. Determination of Molar extinction coefficient of protein.
4. Protein purification by gel filtration, ion-exchange chromatography.
5. Protein separation by SDS-PAGE.
6. Qualitative and Quantitative Analysis of Carbohydrates, Amino acids and proteins,¬ lipid and nucleic acid.
7. Separation of amino acids and sugars by TLC.
8. Extraction of proteins, RNA and DNA from Biological Sources.
9. Laboratory Safety and Sterilization Techniques
10. Brightfield and fluorescence microscopy
11. Staining techniques: Gram staining, acid-fast staining, spore staining, capsule staining
12. Aseptic techniques, Media Preparation, Streak plate, pour plate, and spread plate methods (soil, water, air).
13. Study of composition and use of important differential media for identification of pathogenic bacteria: EMB Agar, McConkey agar, Mannitol salt agar, Deoxycholate citrate agar, TCBS
14. Growth curve analysis: lag, log, stationary, and death phases
15. Measuring bacterial growth: optical density (OD), viable count (CFU)
16. Effect of temperature and pH on growth of E. coli
17. Demonstration of the thermal death time and decimal reduction time of E. coli
18. Mutagenesis: chemical, UV, and transposon mutagenesis
19. Bacterial conjugation, transformation, and transduction
20. Antibiotic susceptibility testing (Kirby-Bauer, MIC determination)

21. Isolation and enumerate of Bacteriophages (PFU) from water/sewage samples using the double agar layer technique.
22. Identification of fungal species.
23. Antifungal susceptibility testing.

Text books:

- Jayaram, J, (1981). Laboratory manual in Biochemistry. *Wiley Eastern.*
- Mu P, Plummer DT. (2011), Introduction to practical Biochemistry, *Tata Mcgraw-Hill Education, CRC Press, USA.*
- Ed. Brenner, Don (2005). J. Bergey's Manual of Systematic Bacteriology. J. Vol. 2, *Springer Publisher, USA*.
- James G (2013). Cappuccino and Natalie Sherman Microbiology: A Laboratory Manual Eds. *Pearson Benjamin Cummings; 10th Edition*.

Elective Theory I: 24PBT201 - INTRODUCTION TO OMICS TECHNOLOGY

Contact Hours/Week: 04 **Credits: 04**
Internal Mark: 40 **External Mark: 60**

Course Outcomes:

UNIT	CO. No.	UPON COMPLETION OF THIS COURSE THE STUDENTS WILL BE ABLE TO	COGNITIVE LEVEL
Unit-I	**CO1**	Understand the Genomics and Proteomics	K1 –K3
Unit-II	**CO2**	Gain proficiency in Metabolomics.	K1 - K4
Unit-III	**CO3**	Acquire knowledge of Meta Transcriptomics.	K1 –K5
Unit-IV	**CO4**	Describe the Single Cell Omics and Applications	K1 - K5
Unit-V	**CO5**	ApplyTranscriptomicsapproachestovariousbiologicalandMedicalresearch	K1 - K6

K1- Remember **K2** – Understand **K3** – Apply **K4**- Analyze **K5**- Evaluate **K6**- Create

SYLLABUS

Unit I: Genomics

Introduction to NGS Sequencing–Illumina Technology, Denovo sequencing or Resequencing; Exome sequencing; RNA sequencing; Small RNA sequencing; Metagenomics; NGS workflow: Exome/ gene panel capture; Ribosomal RNA depletion (RNA-Seq) and small RNAenrichment;16SrRNA based sequencing for metagenomics; Data format, Quality control- Phred score; Fast QC, data analysis tools and pipeline, Read length, read depth, sequence coverage. Annotation Variant Calling etc., Micro arrays and Data mining, GEO Dataset analysis

Unit II: Metabolites and Metabolomics

Metabolomics-An overview, basic sample preparation strategies- extraction, derivatization. Workflow for lipidomics (MS based Lipidomics); Introduction to mass spectrometry and modes of data acquisition, data repositories. Targeted *Vs* Untargeted metabolomics; development of targeted assays for small molecules. Peak detection, retention time alignment; identification of molecular features and metabolites; and structural confirmation of metabolites. Applications of metabolomics in Alzheimers, CVD, Renal disease studies, Food Science and Nutrition.

Unit III: Metagenome and Meta transcriptome:

Basics of16SrRNA and its data analysis, clustering/phylogenetic tree based of alignment, Annotation of metagenome by various properties including phage, plasmid, CRISPR spacer, anti-microbial genes. Tools for Transcriptomics.

Unit IV: Single Cell Omics:

Methods of Single Cell Isolation – Micromanipulation, Immunopanning, FACS, Magnet activated cell sorting, Laser Microdissection, Method of single-cell type nuclei,

Isolation of cell specific molecules, Single Cell Analysis – Genomics, Epigenomics, Transcriptomics, Proteomics, Metabolomics – Applications. Single cell omics in diagnosis and testing, Single cell phenomics, Single cell genome editing – CRISPR/Cas, Data analysis in single cell sequencing, single cell omics for circulating 7hourstumour cells, single cell omics in breast cancer, CVD, metabolic disorders, autoimmune disorders, drug discovery, cell based medicine and therapy and in plants.

Unit V: Transcriptomics:

Gene expression; microarray data analysis: RNA-seq data, lncRNA, siRNA from RNAseq data, Microarray databases (GEO, Array express etc.), and data -file formats. Transcriptomics in drug design and Pharmaceutical Research. Transcriptomics Disorders - Neurodegenerative Disorders – Parkinson's, Alzheimer's and Huntington's Diseases. Human cancer – Breast, Lung etc., Transcriptomics and Phylogenetics applications. Bioconductor. Transcriptomics Case Study

Textbooks:

- Unit-1- Brown T.A, (2002*), Genome,4th Edition*, Garland Science.
- Unit-2 - Quinn G.P and Keough M.J, (2002). *Experimental design and data analysis for biologists*; Cambridge University Press.
- Unit-3 –Knudsen. S, (2004), *Guide to analysis of DNAmicroarraydata;2nd edition*, Wiley-Blackwell.
- Unit-4 - Pevsner, J. (2003), *Bioinformatics and Functional Genomics;* John Wiley and Sons, New Jersey, USA.
- Unit-5- Sandy B., Primrose and Richard Twyman (2009). *"Principles of Genome Analysis and Genomics "*Wiley-Blackwel. l

Elective Theory II: 24PBT214 - PHARMACEUTICAL BIOTECHNOLOGY

Contact Hours/Week: 04 **Credits: 04**
Internal Mark: 40 **External Mark: 60**

Course Outcomes:

UNIT	CO. NO.	UPON COMPLETION OF THIS COURSE THE STUDENTS WILL BE ABLE TO	COGNITIVE LEVEL
Unit-I	**CO1**	Acquire knowledge about sources of drugs	K1 –K3
Unit-II	**CO2**	Describe drug delivery and drug targeting	K1 – K3
Unit-III	**CO3**	Understand the drug development process	K1 –K5
Unit-IV	**CO4**	Analyse Drug Metabolism	K1 – K4
Unit-V	**CO5**	Understand the Drug Regulations and Guidelines	K1 - K6

K1- Remember **K2** – Understand **K3** – Apply **K4**- Analyze **K5**- Evaluate **K6**- Create

SYLLABUS

Unit1: Introduction to Pharmaceuticals:

Discovery of biopharmaceuticals. Source of drugs–plant, animals, microbes and minerals. Drug isolation and evaluation. Drug metabolism–Pharmacokinetics–Absorption, Distribution, Metabolism and Excretion (ADME), Pharmacodynamics–Mechanism of drug action. Drug receptors-G-protein coupled receptors (monomeric transmembrane proteins), small molecule receptors, ligand-gated ion channels (oligomeric transmembrane proteins), transporters (multi-transmembrane proteins).

Unit 2: Pharmacology of drugs:

Physicochemical Properties in Relation to Biological Action, Drug Targets, Basic terminologies in drug delivery and drug targeting, Validation techniques of Pharmaceutical targets, Drug Toxicity. Doses forms, various routes of administration of drugs and Effects of route of administration, Vaccines & Monoclonal antibody-based pharmaceuticals, Antibiotics, Characterization and Bioanalytical aspects of Recombinant proteins as pharmaceutical drugs.

Unit3: Overview Of Drug Development Process:

Initial product characterization**,** Genomics and related technologies upon drug discovery. Gene chips, proteomics, structural genomics, pharmacogenetics. Preclinical studies. Toxicity studies–reproductive toxicity and teratogenicity, mutagenicity, carcinogenicity and other tests, clinical trials, clinical trial design, trial size design and study

population.

Unit 4: Drug discovery methods:

Drug Discovery Process - biological activity directed and other types of screening, natural products, combinatorial chemistry; Methods of Drug Discovery and development-QSAR and SAR. Concepts of Bio availability, Process of drug absorption, Pharmacokinetic processes, Timing for optimal therapy, Drug delivery considerations for the new biotherapeutics.

Unit 5: Drug Formulations and Regulations:

Formulation of Biotechnological Products, Examples of some Biotechnological products in clinical development. Drug Regulations**:** The Regulation of Pharmaceutical Biotechnological Products, Role of FDA, ICH, CDSCO, Guidelines and Ethical Issues.

Text Books:

- Unit-1- Hillery A.M, Lloyd A. Wand Swarbrick. J, (2001), *Drug Delivery and Targeting*, Harwood Academic Publisher.
- Unit-2- Ansel, L.V. Allen and Popovich N.G, Lippincott, (2006), *Pharmaceutical Dosage Forms and Drug Delivery Systems,* Williams and Wilkins Publisher.
- Unit-3- CrommelinDJA, Sindelar R.D, Meibohm. B. (2019). *Pharmaceutical Biotechnology Fundamentals and Applications.5th Edition*, Sindelar *Bernd* Meibohm *Editors.*
- Unit -4- OrlilckiR, CiencialaC, KrylovaL. P, Pielichowski. J, Zaikov. G. E. (2013). *Pharmaceutical and Medical Biotechnology New Perspectives, Russian Academy of Sciences,* Moscow, Russia. Jan *Pielichowski*, *Zaikov* (Editor).
- Unit-5- Antoine Al-Achi, Mali Ram Gupta, William Craig Stagner. (2013). *Integrated Pharmaceutics-Applied Preformulation, Product Design, and Regulatory Science*,1st edition Wiley.

SEMESTER II

Core Theory IV: 24PBT104- ADVANCES IN IMMUNOLOGY AND IMMUNOTECHNOLOGY

Contact Hours/Week: 04 **Credits: 04**

Internal Mark: 25 **External Mark: 75**

Course Outcomes:

Unit No	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit –I	CO1	Acquire knowledge about comprehensive understanding of the structure and functions of the immune system	K1-K4
Unit -2	CO2	Explain the roles of T and B cells and how they interact to protect the body from infections and diseases	K1-K4
Unit -3	CO3	Demonstrate an understanding of key immunological processes such as antigen-antibody interactions, immune responses, and immune tolerance	K1-K4
Unit -4	CO4	Evaluate the mechanisms behind immune system disorders, including autoimmune diseases, allergies, and immunodeficiencies	K1-K5
Unit -5	CO5	Develop critical thinking skills to address immunological challenges, design experiments, and interpret data in both theoretical and applied contexts.	K1-K6

K1-Remember; **K2**-Understand; **K3**-Apply; **K4**-Analyze; **K5**-Evaluate; **K6**-Create

SYLLABUS

UNIT – I: IMMUNE SYSTEM:

History of Immunology, Immunity – Innate, Acquired, Cell mediated and Humoral immunity, Cells of the immune system- lymphocytes, macrophages, mononuclear phagocytes-Dendritic cells, granulocytes, NK cells and Mast cells Central and Peripheral lymphoid organs-Thymus, bone marrow, spleen, lymph node, MALT and GALT. Haematopoiesis, ABO Blood Group System.

UNIT – II: MOLECULAR BASIS OF IMMUNOLOGY: T Cell, helper cytotoxic DC4 and CD8

Detailed structure and development of T and B cell – receptors. cellular adhesion molecules (ICAM, VCAM, selectins, integrins). Activation and Maturation of T and B cell. Organization of the genes for T and B cell receptors. Genetic organization of MHC Molecules, HLA-1 and HLA-2. Peptide loading and expression of MHC-I and MHC-II molecules. Interaction of T and B cells.

UNIT – III: IMMUNE MECHANISMS:

Complement system: Basics of complement protein - Different pathways of complement activation - classical and alternative. Hypersensitivity reaction and their types. Auto-immune disorders, transplantation and cancer immunology. Deficiencies/defects of T cells, B cells and phagocytic cells. Immunity to tuberculosis, malaria and HIV.Microbiome and immunity.

UNIT – IV: ANTIGEN ANTIBODY INTERACTION AND IMMUNO TECHNIQUES:

Antigen – Types, (Haptens) Antigen recognition, processing and presentation. Antibody – Types, Rearrangement of genes in antibody formation - Molecular mechanisms responsible for generating diversity of antibodies in T-cell receptors. Antigen Antibody reactions - Precipitation, agglutination, complement fixation, Flow Cytometry, RIA, ELISA, Western Blotting and Immunofluorescence. Hybridoma Technology – MCA and PCA,

UNIT – V: IMMUNOTHERAPEUTICS:

Immunization practices- active and passive immunization. Vaccines: killed and attenuated, recombinant vaccines, DNA, peptide vaccines and Edible Vaccines. Cell based Therapeutics

Text Books:

- Webstar, Text Book of Clinical Immunology, 2nd Edition, American Academic Publisher (2023). (Unit-1)
- Kuby, Immunology, 8thEdition, W.H. Freeman (2018). (Unit-2)
- Gupta P.K, Essentials of Immunology, 5thEdition, Rastogi Publications (2010).(Unit-3).
- Annadurai B. A, Textbook of Immunology and Immunotechnology, 4th Edition S Chand &Company (2010) (Unit-4)
- Roitt, Essential Immunology, 13thEdition, Wiley and Blackwell Publication (2016) (Unit-5).
- Reference Books:
- Delves P.J, JartinI. S. and Burton I. D. R, Essential Immunotechnology, 12thEdition (2006).
- Goldsby R.A. Kindt T.I and Osborne B.A Kuby Immunology 4thEdition.WHFreeman & Co, NY. (2000).
- Riot. E. Essential Immunology, 12th Edition. Wiley& Blackwell.(2011).
- Timothy Hybridoma technology in the Biosciences and Medicine–Springer Plenum Press.(1985)
- Robert M. Chanock, Fred Brown, Richard A. Lerner. Vaccines: New approaches to immunization. Cold Spring Press. (1986).

E- References:

1. https://courses.lumenlearning.com/biology2xmaster/.../adaptive-immune-response/
2. https://www.medicalnewstoday.com/articles/320101.php

Core Theory V: 24PBT105 - IPR, BIOETHICS AND BIOSAFETY

Hours/Week: 04 **Credit: 04**
Internal Mark: 25 **External Mark: 75**

Course Outcomes:

Unit No	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit -1	CO1	Understand the fundamentals and types IPR	K1-K4
Unit -2	CO2	Acquire knowledge of patent filing procedures, agreements and treaties	K1-K4
Unit -3	CO3	Understand the Bioethics and its Principles	K1-K4
Unit -4	CO4	Understand biosafety and relevant guidelines	K1-K5
Unit-5	CO5	Analyze the genetically modified organisms and related guidelines.	K1-K6

K1-Remember; **K2**-Understand; **K3**-Apply; **K4**-Analyze; **K5**-Evaluate; **K6**-Create

SYLLABUS

UNIT - I

Introduction and the need for intellectual property right (IPR) - Kinds of Intellectual Property Rights: Patent, Copyright, Trade Mark, Design, Geographical Indication, Plant Varieties and Layout Design – Genetic Resources and Traditional Knowledge – Trade Secret - IPR in India and International.

UNIT - II

Patents - Elements of Patentability: Novelty, Non Obviousness (Inventive Steps), Industrial Application - Non - Patentable Subject Matter - Registration Procedure, Rights and Duties of Patentee, Assignment and licence, Surrender and Revocation of Patents, Infringement, Distinction between related rights and copyrights. Concept of Trademarks - Different kinds of marks (brand names, logos, signatures, symbols, well known marks, certification marks and service marks) - Non Registrable.

UNIT – III

History of GATT Agreement – Madrid Agreement – Hague Agreement – WIPO Treaties – Budapest Treaty. PCT – Ordinary and Conventional, Divisional and Patent of Addition – Specifications – Provisional and complete – Forms and fees Invention in context of "prior art" – Patent databases Search - Country-wise patent searches (USPTO, espacenet (EPO). National and International Patent filing procedure – Time frame and cost – Status of the patent. Financial assistance for patenting – Introduction to existing schemes

UNIT – IV

Introduction to Bioethics, History, Significance of Bioethics, Evolution of Bioethics-important timelines, Tuskegee syphilis experiments, Nuremberg trials and code, Guatemala Trials, Willow brook experiments, Principles of Bioethics and Application, CIOMS guidelines, Indian codes of Ethics, ICMR Ethical Guidelines –General and Specific Principles, Act,

Schedule Y, Indian GCP, Clinical Trial Registry of India, Ranjith Roy Choudhry report-Salient features.

UNIT-V

Introduction, Biosafety; Biological Safety Cabinets & their types; Primary Containment for Biohazards; Biosafety Levels of Specific Microorganisms. Biosafety guidelines and regulations (National and International); GMOs/LMOs- Concerns and Challenges; Role of Institutional Biosafety Committees (IBSC), RCGM, GEAC etc. for GMO applications in food and agriculture - HACCP.

Text Books

1. Cooper Donald R, Schindler Pamela S and Sharma JK, "Business Research Methods", Tata McGraw Hill Education, 11e (2012).
2. Catherine J. Holland, "Intellectual property: Patents, Trademarks, Copyrights, Trade Secrets", Entrepreneur Press, 2007.
3. David Hunt, Long Nguyen, Matthew Rodgers, "Patent searching: tools & techniques", Wiley, 2007.
4. Young, T., "Genetically Modified Organisms and Biosafety: A Background Paper for Decision- Makers and Others to Assist in Consideration of GMO Issues" 1st Edition, World Conservation Union, 2004.
5. Bioethics - by Ellen Frankel Paul, Fred D. Miller, Jeffrey Paul, Fred Dycus Miller Cambridge University Press, 2002.
6. Bioethics & Science, John A. Bryant, Linda Baggott la Velle, John F. Searle – 2002.

Reference Books

1. Biosafety and bioethics (2006) Rajmohan Joshi. Gyan Publishing House.
2. Law of Intellectual Property Rights (2016)-Shiv Sahai Singh 8. WTO And Intellectual Property Rights (2007)-Talwar Sabanna
3. IPR: Unleashing the Knowledge Economy (2017)- Prabuddha Ganguli

E-Resources:

https://books.google.co.in/books?id=DYRrngEACAAJ&printsec=frontcover&source=gbs_ge_summary_r&cad=0
https://books.google.co.in/books?id=DKM_k7M8dAUC&source=gbs_book_other_versions
https://books.google.co.in/books?id=1qacDwAAQBAJ&printsec=frontcover

CORE THEORY VI: 24PBT106 - r-DNA TECHNOLOGY

Hours/Week: 04 **Credit: 04**

Internal Mark: 25 **External Marks: 75**

Course Outcomes:

Unit No	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit –I	CO1	Acquire knowledge about comprehensive understanding of the Recombinant DNA Techniques	K1-K4
Unit -2	CO2	Explain the hands-on Skills in Molecular Cloning:	K1-K4
Unit -3	CO3	Demonstrate the Genetic Engineering Applications	K1-K4
Unit -4	CO4	Evaluate the familiarity with Tools for DNA Analysis	K1-K5
Unit -5	CO5	Critical Evaluation of rDNA Technology Advancements	K1-K6

K1-Remember; **K2**-Understand; **K3**-Apply; **K4**-Analyze; **K5**-Evaluate; **K6**-Create

SYLLABUS

Unit I: Basics of rDNA Technology

Restriction, methylation, modification, ligation and manipulation enzymes involved in cloning a gene- Isolation and screening of desired gene -: Plasmids, phagemids, cosmids, Artificial chromosomes, Yeast vectors, Bacillus and Streptomyces vectors Plant Vectors: Ti plasmids, Plant viral vectors – Gemini virus vectors, Caulimo viral vectors, Tobacco virus vectors Animal viral vectors (SV40, Retrovirus, Adenovirus, Adeno associated virus, Vaccinia virus), Baculovirus vectors.

Unit II: Gene Transfer and Detection

Gene Recombination and Gene transfer: Bacterial Conjugation, Transformation, Transduction, Microinjection, Electroporation, Microprojectile, Shot Gun method, Ultrasonication, Liposome fusion, Microlaser - Detection of clones and its expression: yeast two hybrid systems, phage display. DNA labeling techniques- Construction of genomic and cDNA libraries- Screening a genomic library, Cloning Vectors and Expression of Proteins

UNIT III: High-Throughput DNA Sequencing

Preparation of Next Generation Sequencing (NGS) libraries: Fragmentation versus tagmentation, end repair, clonal amplification – Bridge PCR and emulsion PCR. Basics and steps involved in NGS platforms: Illumina/Solexa, Roche 454, Ion-torrent and Pacific biosciences. Current status of Oxford nanopore sequencing. Principles of Mate pair

sequencing, ChIP-seq, RIP/CLIP-Seq, Methyl seq – Restriction enzyme, enrichment and bisulfite treatment strategies.

UNIT IV: Gene Expression Analysis

Overview of gene expression analysis and its significance. Hybridization methods: Southern and Northern. PCR methods: Reverse transcriptase PCR, End point Vs. Real-time PCR, Relative quantitation, Absolute quantification – Standard curve method and digital PCR. Endogenous/loading controls. High throughput analysis: Multiplex PCR, Microarray, Serial analysis of gene expression (SAGE) and Small Amplified RNA-SAGE (SAR-SAGE), Total analysis of gene expression (TOGA), Gene calling, RNA-seq and Ribosome profiling.

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. Antisense and ribozyme technology: application of ribozymes and antisense technologies.

Text and Reference Books

1. Microbial genetics – Friedfelder-1994
2. Principles of gene manipulation – Old and Primrose -1981
3. Genes VII by Lewine-2001
4. Hartl. D.L. A primer of population genetics. III edition, Sinauer associates inc. Sunderland, 2000
5. Molecular cell Biology, Darnell, Lodish, Baltimore, Scientific American Books, Inc., 1994.
6. Molecular and cellular Biology, Stephen L. Wolfe, Wadsworth publishing company, 1993
6. An Introduction to Genetic Engineering by Desmond S. T. Nicholl-2008
7. Genetic Engineering: Manipulating the Mechanisms of Life (Genetics & Evolution) by Russ Hodge and Nadia Rosenthal -2009
8. Principles of Gene Manipulation and Genomics by Sandy B. Primrose and Richard Twyman-2009
9. Gene Cloning and Manipulation by C. J. Howe-2007
10. Genome by T.A. Brown-2002
11.Gene Cloning and DNA analysis by T.A. Brown-2006

E – Resources

https://www.ncbi.nlm.nih.gov/
https://www.amazon.com/Principles-Manipulation-Genomics-Sandy-Primroseebook/dp/B00D88OH7S?dchild=1&keywords=Principles+of+Gene+Manipulation+and+Genomics&qid=1618059356&s=digital-

Core Laboratory – III: 24PBT303 - ADVANCES IN IMMUNOLOGY AND IMMUNOTECHNOLOGY LAB

Contact Hours/Week: 04 **Credits: 04**

Internal Mark: 40 **External Mark: 60**

CO1	Understand the basics of animal handling
CO2	Identify the antiserum and describe about immunoglobulin
CO3	Analyse antigen antibody reaction
CO4	Analyse the separation techniques
CO5	Demonstrate immune techniques

SYLLABUS

1. Demonstration of animal handling for experimental purposes, cervical dislocation, dissection of mice, cardiac puncture, blood sample preparation and its handling

2. Separation of serum and plasma

3. Total and Differential counting of blood cells

4. Separation of mononuclear cells from Human peripheral blood

5. Antigen-Antibody Interactions: Radial Immunodiffusion, Ouchterlony double diffusion Precipitin ring test

6. Agglutination – Blood grouping, Rh factor and Widal test

7. Immunoelectrophoresis and rocket immunoelectrophoresis.

8. Separation of IgG using affinity chromatography

9. Antibody Titre by ELISA

10. SDS-PAGE and Immunoblotting

Text Book

Practical Immunology (4th Edition) by Frank C. Hay and Olwyn M. R. Westwood (2002)
Basic and Clinical Immunology (2nd Edition) by Mark Peakman and Diego Vergani (2009)

Course outcome

Core Laboratory IV: 24PBT304 - r-DNA TECHNOLOGY LAB

Contact Hours/Week: 04 **Credits: 04**

Internal Mark: 40 **External Mark: 60**

CO1	Grasp the fundamental concepts and techniques in recombinant DNA (r-DNA) technology, such as the manipulation of genetic material, gene cloning, and vector systems
CO2	Learn methods for extracting and purifying DNA from various sources (bacterial, plant, animal).
CO3	Perform bacterial transformation (e.g., using *E. coli*) to introduce recombinant DNA and analyze the success of transformation through colony screening
CO4	Gain experience on plasmid analysis through restriction digestion, electrophoresis, and sequencing to confirm the presence of the desired gene insert.
CO5	Learn how to amplify specific DNA sequences using PCR.

SYLLABUS

1. Preparation of plasmid DNA by alkaline lysis method.

2. Isolation of Chromosomal DNA from Biological Sources (Bacteria, Plant and Animal)

2. Agarose gel electrophoresis

3. Restriction enzyme digestion.

4. Ligation.

5. Competent cell preparation

6. Transformation

7. Screening of Recombinants – Antibiotic selection and Blue-White Colonies

8. RAPD

9. RFLP

10. Amplification of DNA – PCR

11. Southern Blotting

Text Book

1. Molecular Cloning: A Laboratory Manual (4th Edition) by Michael R. Green and Joseph Sambrook (2012)

2. Molecular Biology Techniques: A Classroom Laboratory Manual (4th Edition) by Heather Miller, Aysha Divan, and Gail Mickler (2012)

ELECTIVE THEORY III: 24PBT202 - TOOLS AND TECHNIQUES IN BIOINFORMATICS

Hours/Week: 04 **Credit: 04**
Internal Mark: 25 **External Mark:75**
Course Outcomes:

Unit No	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit – 1	CO1	Understand the Algorithms	K1-K4
Unit – 2	CO2	Gain knowledge in phylogenetic tree construction	K1-K4
Unit - 3	CO3	Analyze the Primary and Secondary Structure of Protein	K1-K4
Unit -4	CO4	Perceive the content and signal methods in Protein and gene prediction	K1-K5
Unit-5	CO5	Evaluate Score the matrices with PAM and BLOSUM.	K1-K6

. **K1**-Remember; **K2**-Understand; **K3**-Apply; **K4**-Analyze; **K5**-Evaluate; **K6**-Create

SYLLABUS

UNIT- I: SEQUENCE ALIGNMENT ALGORITHMS:

Definition and Methods of Sequence alignment – Local and Global alignment. Dot matrix – Scoring matrices: PAM and BLOSUM matrices, Dynamic programming Needleman and Wunsch algorithm, Smith-Waterman algorithm – FASTA and BLAST programs – Statistics of alignment score – P value and E value. Methods of Multiple Sequence Alignment-Progressive alignment – Clustal W, T-Coffee, Iterative Method – DIALIGN – Blocks.

UNIT- II: PHYLOGENETIC ANALYSIS:

Phylogenetic tree: Rooted and Unrooted – Methods for phylogenetic tree construction: Character (NJ) and Distance based methods (Maximum Parsimony and Maximum Likelihood method) – Tree evaluation (Bootstrap). PAUP

UNIT III: PROTEIN SECONDARY STRUCTURE PREDICTION:

Protein Secondary structure prediction, UniProtKB, Swiss Prot, TrEMBL, PBD, Chou-Fasman, GOR methods (SOPMA) and Neural network concepts – Nearest Neighbour method –Transmembrane structure prediction.

UNIT- IV: GENE PREDICTION:

Gene finding methods: content and signal methods – Analysis and prediction of regulatory regions – Probabilistic models: Markov chain – random walk – Hidden Markov models – Gene identification and other applications.

UNIT- V: **PRACTICE**:

Dot matrix analysis using Dot matcher. Sequence similarity using BLAST tool. conserved /consensus region sequence using MEME/Interpro. Protein structure prediction and validation- Primary feature computing by PROTPARAM, Secondary structure by SOPMA. Phylogenetic analysis using MEGA

REFERENCES

1. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press, New Delhi 2003.

2. David W. Mount, Bioinformatics – Sequence and Genome analysis, Cold Spring Harbor Laboratory Press, New York, 2001.

3. A. Baxevanis and B.F. Ouellette. Bioinformatics: A practical Guide to the Analysis of Genes and Proteins, Wiley- Interscience, Hoboken, NJ (1998).

4. P.E. Bourne and H. Weissig (Eds.) Structural Bioinformatics, John-Wiley and Sons, 2003.

5. J.Pevsner, Bioinformatics and Functional Genomics, John-Wiley and Sons, 2009.

WEB RESOURCE LINKS

www.Bioinformatics.org

www.bioinfo.mbb.yale.edu/mbb452a/intro/

www.biology.ucsd.edu/others/dsmith/Bioinformatics.html

ELECTIVE THEORY IV: 24PBT214 - BIOPHARMACEUTICALS

Hours/Week: 04 **Credit: 04**
Internal Mark: 25 **External Mark: 75**

Course Outcomes:

Unit No	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit –I	CO1	Knowledge of Biopharmaceutical, Mechanism and Techniques	K1-K4
Unit -2	CO2	Grasp the Biopharmaceutical Drug Development Process	K1-K4
Unit -3	CO3	Apply Regulatory Frameworks in Biopharmaceutical Development	K1-K4
Unit -4	CO4	Evaluate the Latest Innovations in Biopharmaceuticals	K1-K5
Unit -5	CO5	Critical Assessment of Biopharmaceutical Trends and Innovations	K1-K6

. **K1**-Remember; **K2**-Understand; **K3**-Apply; **K4**-Analyze; **K5**-Evaluate; **K6**-Create

SYLLABUS

UNIT I: Drug Absorption and Distribution

Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, Distribution Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT II: Drug Metabolism and Elimination

Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT III: Biosimilars

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 biologicals)/Biosimilars development peptides; Recombinant non glycosylated proteins; Recombinant glycosylated proteins; Industries dealing with biogenerics and its market value; Global scenario.

UNIT 1V: Characterization of Biosimilars

Approaches; characterization and types of biosimilars; 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.

UNIT V: Immunogenecity of Biopharmaceuticals

F and host- related Factors contributing to immunogenicity, Measurement of immunogenicity. Consequence of immunogenicity to biopharmaceuticals;

Text Books:

- Biopharmaceuticals: Manufacturing and Applications (2010), R.P. Gupta Pharma Med Press
- Biopharmaceuticals: An Introduction (2013) P. K. Gupta, CBS Publishers & Distributors
- Biopharmaceuticals: An Introduction to Biopharmaceuticals (2011) K. R. Anantharaman Elsevier
- Biopharmaceuticals: Drug Discovery and Development (2012) S. K. Soni, G. K. Gupta Elsevier
- Pharmaceutical Biotechnology: Concepts and Applications (2012) G. P. Mohanta, A. K. Sahoo Springer
- References:
- Biopharmaceuticals: Biochemistry and Biotechnology (2018). Gary Walsh, Wiley Blackwell
- Biopharmaceutical Drug Design and Development (2007). Gary Walsh, Wiley-Interscience
- Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications (2012), Sandy Fraser, Springer
- Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs (2007), Michael J. Groves, Wiley-Interscience
- Fundamentals of Biopharmaceuticals (2011) Sameer. Z.N. Springer

E-Resources:

- https://pubmed.ncbi.nlm.nih.gov/
- https://www.mdpi.com/journal/pharmaceuticals

Semester III

Core Theory VII: 24PBT107 - PLANT AND ANIMAL BIOTECHNOLOGY

Contact Hours/Week: 05 **Credits: 04**

Internal marks: 25 **External Marks: 75**

Course Outcomes:

Unit No.	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit-I	**CO-1**	Explain the fundamental concepts and techniques used in plant and animal biotechnology, including molecular biology tools and tissue culture methods.	**K1-K4**
Unit-II	**CO-2**	Apply laboratory techniques such as plant tissue culture, gene transfer, and PCR in simulated or real-world settings.	**K1-K4**
Unit-III	**CO-3**	Analyze the development, applications, and limitations of transgenic organisms in agriculture, medicine, and industry.	**K1-K4**
Unit-IV	**CO-4**	Critically evaluate current biotechnological advancements, research papers, and case studies in the field of plant and animal biotechnology**.**	**K1-K5**
Unit-V	**CO-5**	Discuss ethical, environmental, and regulatory issues associated with genetic modification and biotechnology products.	**K1-K6**

K1-Remember; **K2**-Understand; **K3**-Apply; **K4**-Analyze, **K5**-Evaluating, **K6**-Create

SYLLABUS

Unit-I

Scope and importance of plant biotechnology. Totipotency - Tissue culture media - composition and preparation. Callus and suspension culture; Micropropagation; Somaclonal variation; Organogenesis; Somatic embryogenesis; Embryo culture. Artificial seeds. Protoplast fusion and somatic hybridization; cybrids; anther, pollen and ovary culture for production of haploid plants - Secondary metabolite production.

Unit-II

Gene transfer methods in plants: Direct and indirect DNA transfer. Electroporation, microinjection and particle bombardment. Plasmids - Ti plasmids and Ri plasmids. Agrobacterium mediated gene transfer, vector- viral vectors and their applications. Characterization of transgenics - screenable and selectable markers. Marker free methodologies and gene targeting.

Unit-III

Herbicide resistance: phosphoinothricin - weeds. Insect resistance: Bt genes, non-Bt genes like protease inhibitors. Disease resistance: chitinase, antifungal proteins, thionins, PR proteins; Virus resistance: coat protein mediated, nucleocapsid gene. Nematode resistance. Abiotic stress tolerance: drought and flooding, salt and temperature. Post-harvest losses: long shelf life of fruits and flowers, use of ACC synthase, polygalacturanase, carbohydrate composition and storage, ADP glucose pyrophosphatase.

Unit-IV

Brief history of animal cell culture; cell culture media and reagents; culture of

mammalian cells, tissues and organs; primary culture, secondary culture, continuous cell lines, suspension cultures; Reproductive Biotechnology- structure of sperm and ovum, cryopreservation of gametes and embryos in mammals. Embryo transfer-Artificial insemination, ICSI, super ovulation, embryo recovery, *In vitro* fertilization, embryo splicing and embryo transfer technology

Unit-V

Animal disease and diagnosis - application of probes for disease diagnosis of existing and emerging animal diseases. Hybridoma techniques - MCA and PCA. Prophylaxis – production of vaccines such as Oral& DNA Vaccines in animal disease. Application of cell culture technology in production of human and animal viral vaccines. Pharmaceutical proteins – Insulin, Growth hormones. Stem Cells- Properties, Types, Therapy, Prospects and Ethics in stem cell research.

Text Books:

1. Plant Biotechnology by B.D. Singh, 4th Edition, (2022) Unit I & II
2. Introduction to Plant Biotechnology by H.S. Chawla 3rd Edition (2009) Unit III
3. Animal Biotechnology Sasidhara R 2nd Edition (2006) Unit IV & V

Reference Books:

1. Principles of Gene Manipulation and Genomics by S.B. Primrose and R.M. Twyman.7thEdition (2006).
2. Molecular Biotechnology: Principles and Applications of Recombinant DNA by Bernard R. Glick, Jack J. Pasternak, and Cheryl L. Patten. 4thEdition (2010).
3. Plant Biotechnology and Genetics: Principles, Techniques, and Applications by C. Neal Stewart,2nd Edition. (2016).
4. Frontier Technologies in Bovine Reproduction by A. Kumaresan and A.K. Srivastava. 1st Edition. (2022).
5. Stem Cells: Scientific Facts and Fiction by Christine L. Mummery et al. 3rd Edition. (2020).

E-references:

1. https://www.gurukpo.com/animal-biotechnology
2. https://www.barnesandnoble.com/w/biotechnology-for-animal-health-chandrabhaga-desai/1146872995
   https://arch.pin67321d.my/request/media/m3yedr8Z56SP83azm6rmmEQT/Introduction_To_Plant_Biotechnology_Hs_Chawla. zip

Core Theory VIII: 24PBT108 - BIOPROCESS TECHNOLOGY

Contact Hours/Week: 05 **Credits: 04**

Internal marks: 25 **External Marks: 75**

Course Outcomes:

Unit No.	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit-I	**CO-1**	Understand the principles of biochemical engineering and microbial growth kinetics.	**K1-K4**
Unit-II	**CO-2**	Design and operate bioreactors for various fermentation processes.	**K1-K4**
Unit-III	**CO-3**	Apply downstream processing techniques for bio-product recovery and purification	**K1-K5**
Unit-IV	**CO-4**	Analyze the enzymes in food processing and production.	**K1-K5**
Unit-V	**CO-5**	Applications of microbes in food processing and production.	**K1-K6**

K1-Remember; **K2**-Understand; **K3**-Apply; **K4**-Analyze; **K5**- Evaluate; **K6-**Create

SYLLABUS

UNIT – I

Screening of industrially important microbes – Primary and Secondary screening. Strain improvement for increased yield and other desirable characteristics. Preservation of Microbes. Mathematical expression of bacterial growth, generation time and growth rate. Batch, continuous and synchronous cultures. Diauxic growth and factors affecting microbial growth. Stress response. Microbial death curve under adverse conditions.

UNIT – II

Bioreactor design and types of Fermentation. Design and configuration - mechanically agitated, pneumatic and hydrodynamic fermenters. Concepts & basic modes of fermentation - Batch, fed batch and continuous fermentation. Conventional fermentation versus biotransformation. Solid substrate, surface and submerged fermentation. Fermenter design - mechanically agitated, pneumatic and hydrodynamic fermenters. Large scale animal and plant cell cultivation and air sterilization

UNIT – III

Upstream processing - media formulation, sterilization, aeration and agitation. Measurement and control of bioprocess parameters, scale up and scale down process. AI Technology in fermentation process**.** Bio separation - filtration, centrifugation, sedimentation, flocculation, microfiltration, sonication. Cell disruption – enzymatic lysis and liquid-liquid extraction. Purification by precipitation (ammonium sulfate, solvent), electrophoresis and crystallization. Extraction (solvent, aqueous two phase, super critical) and chromatographic

techniques. Reverse osmosis and ultra filtration. Drying, crystallization, storage and packaging.

UNIT – IV

Mechanism of enzyme function and reactions in food processing. Enzymic bioconversions - starch and sugar conversion processes. syrup, hydrolyzed protein and their downstream processing. Baking by amylases, deoxygenation and de-sugaring by glucose oxidase, beer mashing and chill proofing; cheese making by proteases and various other enzyme catalytic actions in food and Dairy processing.

UNIT – V

Fermented foods and beverages, food ingredients and additives used in fermentation and their purification. Microbes and their use in pickling, producing colours and flavours, Wine, beer Ethanol, Butanol, acetone and hydrogen. Bacteriocins from lactic acid bacteria. Citric acid and amylase, vitamins, Antibiotics.

Text books:

1. Bioprocessing: An Introduction by E. R. D. S. R. Sharma, 2014 (3rd Edition)
2. Principles of Fermentation Technology by Peter F. Stanbury, Alan Whitaker, & Stephen J. Hall, 2016 (3rd edition)

Reference Books:

1. Stanbury, P. F., & Whitaker, A. (2010). Principles of Fermentation Technology. Oxford: Pergamon Press.
2. El-Mansi, M., & Bryce, C. F. (2007). Fermentation Microbiology and Biotechnology. Boca Raton: CRC/Taylor & Francis

e-Resources:

1. https://www.gurukpo.com/bioprocess technology-
2. https://www.barnesandnoble.com/w/biotechnology-for- microbial biotechnology-chandrabhaga-desai/1146872995
3. https://arch.pin67321d.my/request/media/m3yedr8Z56SP83azm 6rmmEQT/Introduction_To_Plant_Biotechnology_Hs_Chawla. zip

Core Theory IX: 24PBT109 - Research Methodology & Critical Analysis of Classical Papers

Contact Hours/Week: 04 **Credits: 04**

Internal marks: 25 **External Marks: 75**

Course Outcomes:

Unit	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit-I	CO-1	Identify and explain various research methodologies, including qualitative, quantitative, and mixed-method approaches.	**K1-K4**
Unit-II	CO-2	Develop a structured research proposal, including problem identification, hypothesis formulation, and selection of appropriate research design and methods.	**K1-K4**
Unit-III	CO-3	Apply appropriate tools and techniques for data collection, statistical analysis, and result interpretation using software where applicable.	**K1-K4**
Unit-IV	CO-4	Critically analyze classical and contemporary research papers, focusing on research design, data interpretation, and scientific impact.	**K1-K5**
Unit-V	CO-5	Demonstrate proficiency in academic writing, referencing, and ethical considerations in research communication and publication.	**K1-K6**

K1-Remember; **K2**-Understand; **K3**-Apply; **K4**-Analyze, **K5**-Evaluating, **K6**-Create

SYLLABUS

Unit I

Structure and Components of Scientific Reports – Types of Report – Technical Reports and Thesis – Significance – Different steps in the preparation – Layout, Structure and Language of Typical Reports – Illustrations and Tables – Bibliography, Referencing and Foot Notes.

Unit II

Identification of research problems – Methods of literature collection and review – Planning and execution of investigation – Thesis writing – Preparation of research papers- Ethics in thesis writing.

Unit III

Research proposal and its elements Formulation of research problem-criteria of sources and definition Development of objectives and characteristics of objectives. Development hypothesis and applications. Time frame and Work Plan – Budget and Justification – References.

Unit IV

Academic writing, sources of information, assessment of quality of journals and articles, writing scientific report, structure and component of research report, types of report –

technical reports and thesis, SCOPUS Index, citations, search engines beyond google, impact factor, H- Index.

Unit V:

Selection of seminal papers across different fields, Techniques for critical analysis: Identifying hypothesis, assumptions, and conclusions, Evaluating methodologies and interpretations, analyzing logical structure and use of evidence, Group discussions and presentations based on selected papers, Data Processing and Analysis.

Text books:

1. Research Methodology: A Step-by-Step Guide for Beginners by Ranjit Kumar - 2014 (4th edition)
2. Research Methodology: Methods and Techniques by C.R. Kothari - 2024 (5th revised edition) New age International Pvt Ltd publisher.

Reference Books:

1. The Craft of Research by Wayne C. Booth, Gregory G. Colomb, Joseph M. Williams - 1995 (1st edition), 2003 (2nd edition), 2008 (3rd edition), 2016 (4th edition)
2. Case Study Research: Design and Methods by Robert K. Yin - 1984 (1st edition), 1994 (2nd edition), 2003 (3rd edition), 2009 (4th edition), 2014 (5th edition)

E-resources:

https://methods.sagepub.com

https://www.doaj.org

CORE LABORATORY V: 24PBT305 - PLANT AND ANIMAL BIOTECHNOLOGY LAB

Contact Hours:04 **Credits: 02**

Internal Marks: 40 **External Marks :60**

Course Outcomes

CO	Upon Completion of this course, the students will be able to	Cognitive Level
CO1	Understand the composition and preparation of Murashige and Skoog (MS) medium and other stock solutions for plant tissue culture.	K3-K4
CO2	Demonstrate the ability to induce callus formation from various plant explants such as leaf, root, bud, and shoot apex under sterile conditions.	K3-K4
CO3	Isolate single-cell suspensions from chicken liver (primary culture) and spleenocytes using appropriate enzymatic digestion and mechanical dissociation.	K3-K4
CO4	Perform cell counting and assess cell viability using vital stains such as Trypan blue, Erythrosin, and Giemsa.	K3-K4
CO5	Conduct MTT assays to evaluate cytotoxicity and cell proliferation in cultured animal cells.	K3-K4

K3- Apply**; K4**- Analyze

SYLLABUS

1. Preparation of stocks - Preparation of Murashige and Skoog medium
2. Generation of Callus – Leaf, root, bud and shoot apex
3. Maintenance of callus culture.
4. Cell suspension culture
5. Anther culture
6. Pollen culture
7. Embryo culture Micro propagation of plants by nodal and shoot tip culture
8. Agrobacterium-mediated gene transformation by co-cultivation method
9. Protoplast isolation (Physical, Chemical and enzymatic method)
10. Protoplast cell counting and viability studies
11. Protoplast fusion – Physical and Chemical Method

DBT STAR Programme Additional Practical

1. Protoplast Culture
2. Preparation of culture media with various supplements for animal tissue culture.
3. Preparation of single cell suspension from chicken liver (Primary cell culture)

4. Spleenocytes Isolation
5. Cell counting and viability - staining of cells (a) Vital Staining (Trypan blue, Erythrosin (b) Giemsa staining.
6. MTT Assay

Text books:

- Plant Biotechnology: Laboratory Manual by R. S. S. Rajaraman, 2018 (2nd Edition)
- Principles and Techniques of Biochemistry and Molecular Biology by Keith Wilson, John Walker, 2015 (3rd Edition)
- Animal Biotechnology: Lab Manual **by** A. M. Khanna, M. M. J. Lata, 2017 (1st Edition)
- Practical Applications of Plant Molecular Biology by J. W. Galbraith, H. G. Krentz,2016 (2nd Edition)

Computing Laboratory VI: 24PBT306 - BIOPROCESS TECHNOLOGY LAB

Contact Hours/Week: 04 **Credits: 02**

Internal Marks: 40 **External Marks: 60**

Course Outcomes:

Unit No.	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit-I	CO-1	Demonstrate proficiency in aseptic techniques and microbial culture handling for bioprocess experiments.	**K3-K4**
Unit-II	CO-2	Quantify microbial growth parameters and analyze kinetics using experimental data.	**K3-K4**
Unit-III	CO-3	Operate and troubleshoot basic bioprocess equipment such as fermenters, centrifuges, and spectrophotometers.	**K3-K4**
Unit-IV	CO-4	Design and conduct experiments to optimize culture conditions for microbial or enzymatic production.	**K3-K4**
Unit-V	CO-5	Execute downstream processes like filtration, centrifugation, and protein precipitation for product recovery.	**K3-K4**

K3-Apply; **K4**-Analyze

SYLLABUS

1. Screening of industrially important microorganisms.
2. Microbial growth kinetics
3. Isolation of actinomycetes for antibiotic production.
4. Isolation and enumeration of lactic acid bacteria.
5. Lactic acid Production and estimation
6. Citric acid Production and estimation
7. Ethanol production and estimation by yeast
8. Beer production by yeast – setting up a lab experiment
9. Wine production by yeast – setting up a lab experiment
10. Immobilization of microbes by sodium alginate method
11. Batch, CSTR and Fed-batch fermentation.
12. Assembly of bioreactor and sterilization.
13. Antibiotic production – Penicillin and Streptomycin
14. Amylase Production and estimation

Text Books:

1. Bioprocess Engineering: Downstream Processing by Pau Loke Show et al. (2024) CRC Press, ISBN: 9780429466731.

2. Bioprocess Engineering and Technology: Fundamentals by Biswanath Bhunia et al. (2025) Taylor & Francis Publisher: ISBN: 9780367675622.

Reference Books:

1. Practical Biotechnology by Dr. G.D. Gupta, Dr. R.S. Gaud, and S.B. Gokhale (2023), 11th Edition, Nirali Prakashan Publishers, ISBN: 9788185790657.

E-Resources:

https://www.youtube.com/watch?v=c_eI0Yq51w4

https://www.youtube.com/watch?v=pTkCJoL_HUo

https://www.youtube.com/watch?v=yTnQrh36S58

https://www.youtube.com/shorts/R6EjKANvhSc

https://www.youtube.com/watch?v=Uut1cUs6GpA

Semester VI

Elective Theory V: 24PBT203 - PROTEIN THERAPEUTICS AND DRUG DELIVERY SYSTEM

Contact Hours/Week: 04 **Credits: 04**

Internal Marks: 25 **External Marks: 75**

Course Outcomes:

Unit	CO	Upon completion of this course the students will be able to	Cognitive Level
Unit 1	CO 1	Explain the fundamentals of protein therapeutics and their classification, mechanism of action and clinical applications	K1-K5
Unit 2	CO 2	Analyze various drug delivery systems	K1-K5
Unit 3	CO 3	Evaluate the stability, formulation and challenges	K1-K6
Unit 4	CO 4	Compare and contract administration of protein therapeutics	K1-K6
Unit 5	CO 5	Interpret regulatory guidelines and quality control measures	K1-K6

SYLLABUS

Unit I: Fundamentals of Protein Therapeutics

Introduction to biopharmaceuticals and their significance. Recombinant protein production and purification. Therapeutic monoclonal antibodies and their engineering. Case studies on FDA-approved protein drugs.

Unit II: Pharmacokinetics and Stability of Protein Drugs

Absorption, distribution, metabolism, and excretion (ADME) of protein drugs. Stability challenges: aggregation, denaturation, and immunogenicity. Advances in formulation technologies: PEGylation, fusion proteins, and cryoprotection.

Unit III: Drug Delivery Systems for Biopharmaceuticals

Controlled release systems: hydrogels, microspheres, and implants. Nanoparticle-based delivery: polymeric nanoparticles, liposomes, exosomes. Targeted delivery approaches: antibody-drug conjugates (ADCs), receptor-mediated endocytosis. Clinical applications of smart drug delivery systems.

Unit IV: Regulatory Aspects & Commercialization of Protein Drugs

FDA, EMA, and ICH guidelines for protein-based drug approvals. Intellectual property rights and patent filing for biopharmaceuticals. Case studies on successful protein therapeutics startups. Future trends in biosimilar and biobetters development.

Unit V: Future Trends in Protein Therapeutics

AI in drug discovery and formulation optimization. Personalized protein therapeutics. Machine learning in pharmacokinetic modeling. Advances in 3D bioprinting of protein scaffolds.

Textbooks:

1. Text Book of Pharmaceutical Formulation Development of Peptides and Proteins (Protein Therapeutics: A Comprehensive Guide) – Lars Hovgaard et al., Publisher- CRC Press (Taylor & Francis Group), Second Edition.
2. Text Book of "Drug Delivery: Principles and Applications" – Binghe Wang & Teruna Siahaan, Publisher- John Wiley & Sons, Second Edition (2016).

Reference Books:

1. Text Book of "Nanotechnology for Drug Delivery" (Volume One: Nanoplatforms in Drug Delivery) – José Luis Arias, Publisher- CRC Press (Taylor & Francis Group), First Edition.
2. Text Book of "Advances in Protein Chemistry and Structural Biology" – David S. Goodsell, Publisher- Academic Press (Elsevier), This is an ongoing series with multiple volumes.

E-Resources:

Biopharmaceutical Production

Drug Stability & Pharmacokinetics

Elective Theory VI: 24PBT215 - APPLICATIONS OF COMPUTATIONAL BIOLOGY

Contact Hours/Week: 04 **Credits: 04**

Internal Marks: 25 **External Marks: 75**

Course Outcomes (COs)

Unit No.	CO. No.	Upon completion of this course, the students will be able to	Cognitive Level
Unit-I	CO-1	Explain fundamental computational biology concepts and tools used in genomics, transcriptomics, and proteomics.	K1-K4
Unit-II	CO-2	Apply sequence alignment, genome annotation, and structural prediction tools to analyze biological datasets	K1-K4
Unit-III	CO-3	Interpret and visualize the results of computational analyses to derive meaningful biological insights.	K1-K4
Unit-IV	CO-4	Evaluate computational methods and algorithms used in biological research through literature review and case studies.	K1-K5
Unit-V	CO-5	Design and execute a mini-project that integrates computational biology techniques to address a specific biological problem.	K1-K6

Cognitive Level Key: K1-Remember; **K2**-Understand; **K3**-Apply; **K4**-Analyze, **K5-**Evaluating, **K6-**Create.

SYLLABUS

UNIT: I

Introduction to computational biology, scope and significance; Computational Genomics; Genome assembly and annotation; Comparative genomics; Structural and functional genomics; Variant calling and SNP analysis; Genome-wide association studies (GWAS). Bio database & Tools: Ensembl, UCSC Genome Browser, NCBI, BLAST, BEDTools.

UNIT: II

Sequence alignment (pairwise, Local, Global & Multiple); Scoring matrix; RNA sequencing (RNA-Seq) analysis pipeline; Isoform quantification and alternative splicing; Co-expression networks and gene regulatory networks. Bio database & Tools: STAR, HISAT2, Cufflinks, DESeq2, GEO, Array Express.

UNIT: III

Computational Proteomics Overview; Protein structure prediction and modelling; Protein identification using mass spectrometry data; Post-translational modifications analysis; Function annotation and genome mapping; Protein-protein interaction and STRING.

UNIT: IV

Introduction to Metabolomics and Systems Biology; Metabolite identification and quantification; Computational approaches in metabolite pathway analysis; Integration of multi-omics data (genome, proteome, metabolome); Metabolic network modelling. Bio database & Tools: KEGG, HMDB, MetaboAnalyst, BioCyc.

UNIT: V

NGS Technologies and Platforms; NGS data formats (FASTQ, BAM, VCF); Quality control and preprocessing of NGS data; Variant discovery, genome re-sequencing, and epigenomics; Single-cell sequencing data analysis. Bio database & Tools: FastQC, GATK, Bowtie2, BWA, SAMtools.

Textbook and References

Textbooks

1. *Computational Biology: A Practical Introduction to BioData Processing and Analysis with Linux, MySQL, and R* by Röbbe Wünschiers, 2013, Springer publication
2. *Introduction to Computational Biology* by Sriram K, 2025, Kindle Publication

Reference Books

1. *Textbook Of Bioinformatics, A: Information-theoretic Perspectives Of Bioengineering And Biological Complexes* by Perambur Neelakanda, 2020.
2. *Biological Sequence Analysis Probabilistic Models of Proteins and Nucleic Acids* by Richard Durbin, Sean R. Eddy, Anders Krogh, Graeme Mitchison in 2018

E-references

- https://www.coursera.org/specializations/bioinformatics
- https://www.edx.org
- https://www.youtube.com/user/NCBINLM