RVS COLLEGE OF ARTS & SCIENCE (AUTONOMOUS), SULUR, COIMBATORE-641402

DEPARTMENT OF BIOTECHNOLOGY

M.Sc., BIOTECHNOLOGY

Syllabus effective for the students admitted during the Academic

Year 2023-2024 Batch onwards

(2023-2025)

HOD **PRINCIPAL** **COE**

RATHNAVEL SUBRAMANIAM COLLEGE OF ARTS AND SCIENCE
AUTONOMOUS
REACCREDITED WITH 'A' GRADE BY NAAC
SCHEME OF EXAMINATIONS
M.Sc. BIOTECHNOLOGY
2023-BATCH ONWARDS-BASED ON - CHOICE BASED CREDIT SYSTEM

Semester	Type	Title of the paper	Hours of instructions / week		Credits	Duration of exam in hours	MARKS		
							CIA	EOS	TOTAL
I	M-I	Molecular Cell Biology	4	1	4	3	25	75	100
	M- II	Molecular Genetics of Eukaryotes	4	1	4	3	25	75	100
	M-III	Intermediary Metabolism	4	1	4	3	25	75	100
	M-IV	Immunotechnology	4	1	4	3	25	75	100
	MP-I	Lab in Enzymology, Immunotechnology and Molecular Genetics	5		4	6	40	60	100
	M-V	Introduction to Clinical Trials	4	1	4*	3	25	75	100*
II	M - VI	Chemistry of Proteins and Protein Engineering	4	1	4	3	25	75	100
	M- VII	Fermentation and Industrial Biotechnology	4	1	4	3	25	75	100
	M- VIII	Genetic Engineering	4	1	4	3	25	75	100
	M-IX	Genomics and Proteomics	4	1	4	3	25	75	100
	MP- II	Lab in Recombinant DNA technology and Protein Chemistry	5		4	6	40	60	100
	EL- IA	Introduction to Clinical Data Management	4	1	4*	3	25	75	100*
	EL- IB	Biophysics and Biostatistics	4		4*	3	25	75	00*
	EL- IC	Biochemical Technology	4		4*	3	25	75	100*
	EL-II (PV)	Mini Project Report and Viva Voce**	-		4*	-	40	60	100*
III	M- X	Plant Biotechnology	4	1	4	3	25	75	100
	M- XI	Animal Biotechnology	4	1	4	3	25	75	100
	M- XII	Pharmaceutical Biotechnology	4	1	4	3	25	75	100
	MP- III	Lab in Plant and Animal Biotechnology	6		4	6	40	60	100

	EL-IIA	Project Management, Principles of Pharmacoeconomics and Pharmacogenomics	4	1	4*	3	25	75	100*
	EL-IIB	Molecular Genetics	4		4*	3	25	75	100*
	EL-IIC	Cellular Biochemistry and Oncogenesis	4		4*	3	25	75	100*
	EL-III	EDC [#]- Annexure	4		4[#]	3	25	75	100
IV	**M-XIII**	Biodiversity, Bioethics and IPR (Self Study)	4	1	5	3	25	75	100
	MP-IV	Lab in Pharmaceutical Biotechnology and Bioinformatics	5		4	6	40	60	100
	MP-V (PV)	Project Report and Viva –Voce**	20		5	-	40	60	100
		***Electives** **TOTAL**			**70+ 4[#]** **16* = 90**				**1800 + 400* = 2200**

M – Major Paper; MP-Major Practical; PV- Project Viva; *EL -Electives –Students can opt one out of three in a semester. # EDC-Extra Disciplinary Course

** Project Report and Viva-Voce mark 80:20 respectively will be jointly assessed based on 40:60 ratio application.

EDC:FORENSIC SCIENCE

SEMESTER I

M-I MOLECULAR CELL BIOLOGY

No.	Course Outcome (Cos): After completion of this course, the students will be able to	Pos &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	To describe the techniques involved in separation of cell organelles.	PO1& PS01	12	R
CO2	To describe about the biomembranes.	PO1& PS01	6	R/U
CO3	To describe the process of active transport.	PO1& PS01	6	R/U
CO4	To understand the mechanism of cell-cell interaction.	PO1& PS01	12	R/U
CO5	To extend the process of Protein Trafficking.	PO1& PS01	12	R/U/A
CO6	To explain about the regulation of cell cycle.	PO1& PS01	12	R/U/A

UNIT I: PURIFICATION OF CELLS AND THEIR PARTS LECTURE HOURS: 12

Flow Cytometry - Leukocytes, erythrocytes - fluorescence – FACS,**Centrifugation** - Differential centrifugation , equilibrium density gradient centrifugation, **Organelle Preparation** - Cell fraction, monoclonal antibody, cell surface membrane. **Cytoskeletal Network- Microtubules** - Special transport processes, synthesis in the cell body, **Micro Filaments** - Plasma membrane proteins, cytoskeletal actin, motor proteins, **Intermediate Filaments** - Manifestation of mechanical work, generating movement. **SPECIALISED CELLS- Nerve Cells** - Action potential, transmit the signals to other cells, **Muscle Cells** - Adhesion receptor - large complex with dystrophin, contraction and relaxation, **Tumor Cells** - Grown in suspension as single cells, resistance to several drugs, **Sperm Cells** - Gamete cells, spermatozoon, non-motile sperm. **Activity-Demonstration model for specialized cells** - To develop the demonstration model for specialized cells.

UNIT II: BIOMEMBRANES LECTURE HOURS: 12

Structural Organization - Chemical composition and functions,**Transport of Molecules** - Ions across the cell, selective movement, patch clamping, **Ion gates and channels** - Ion selective and fluctuate between open and closed states,**Voltage gated ion channels** - Absorb nutrients, intestinal epithelium, electric potential, **Neurotransmitters and Signal Transmission** - Electric signals carry information within a nerve cell, chemical signals transmit information, **ACTIVE TRANSPORT- ATPases** - Hydrolysis of ATP, coupled chemical reaction, transport of ions, **Na+ K+ Pump** - Plasma membrane of higher eukaryotes, Apical plasma membrane of Mammalian stomach, **Proton Pump** - Bacterial plasma membrane, Inner mitochondrial membrane, **Chloride Pump** - Na-K-Cl co-transporter, function. **Activity- Working Model on Active Transport** - To create the Active transport working model,**Collection of Articles on Neurotransmitters** - To collect recent research articles for Neurotransmitters.

UNIT III: CELL- CELL INTERACTION AND COMMUNICATION

LECTURE HOURS: 12

Extra cellular matrix - Cell-cell and cell-matrix interactions, lock the cell into the synapse, **Adhesion junctions,Tight junctions,Gap junctions** - Signaling promotes tight adhesion, glycosylated, Cytosols of adjacent, cells to exchange small

molecules,**Plasmodesmata** - Plant cell communication, Annulus, Desmotubule, **Plant Cell Wall** - Comprises layers of cellulose, microfibrils embedded, Hemicellulose, Pectin, Extensin, **Signaling Molecules & Cell surface Molecules** - Control metabolic processes, growth and differentiation of tissues. **G PROTEIN COUPLED RECEPTORS- JAK/STAT Pathway and MAP Kinase pathway** - Growth factors and signal transduction, cytokine receptors,**Ras/Rof pathway** - Monomeric GTP-binding switch protein, mutant Ras proteins, **Activity- Electrical Model on G-Protein Receptor** - To generate the Electrical model for G Protein coupled receptor pathways, **To find the cellulose degrading microorganism from soil sample.**

UNIT IV: PROTEIN TRAFFICKING LECTURE HOURS: 12

Synthesis and Translocation of secretory proteins - Membrane bound intermediate, conversion of VSV G protein from an endoglycosidase D-resistant, **Protein modification and Folding** - Signal sequence cleaved, N-linked glyosylation,**Protein sorting to mitochondria** - Electron-transport proteins, F-class atpase to Synthesize ATP, Amphipathic N-Terminal Signals,**Peroxysome** - Peroxisomal-targeting sequence 1, soluble receptor protein,**Nucleus and chloroplast** - S-subunit precursor, Hsc70 chaperone, **Intracellular traffic** - Membrane glycoprotein, vesicular stomatitis virus, transfection, **Secretion and endocytosis** - Ligands into the cell, cholesterol in the form of lipoprotein, **Activity- Clay model on Protein trafficiking** - To prepare the Clay model for Protein trafficiking

UNITV: CELL CYCLE LECTURE HOURS: 12

Cell cycle Overview - Introduction, G1, M, G2, S phase, cell replication, **Oocyte eggs and early embryos** - Frog ovary, diploid zygote nucleus, meiotic maturation, **Genetic studies with S.pombe** - Catalytic protein kinase subunit, Temperature-sensitive mutants, Phosphorylation of the CDK Subunit, **Regulation of Cell Cycle-Yeast & Mammalian cell** - S. Cerevisiae, cyclin-dependent kinase, mammalian restriction point, **Cell cycle check points** - Control mechanisms, unreplicated-DNA checkpoint, spindle-assembly checkpoint, **Mitosis and meiosis** - Repression of G1 Cyclins, Metaphase I & II, Anaphase I & II,**Programmed Cell Death** - Regulated process, Apoptosis, Necrosis, **Activity- Model on Cell Cycle** - To develop the cell cycle model by using Stick & Ball method.

Text Books:

T1. Molecular Biology of the Cell ,Edition:5 ,Garland Science ,Alexander Johnson et al and Bruce Alberts(2007).
T2. Molecular Cell Biology, Edition:5, W. H. Freeman ,Arnold Berk et al and Harvey Lodish(2003).
T3. Principles Of Cell Biology,Edition:1 ,Jones & Bartlett Learning , George Plopper(2011).

Reference Books:

R1. The cell – A molecular approach ,Edition:5 ,Sinauer Associates, Inc , Geoffrey M. Cooper AND Robert E. Hausman (2009).

M-II MOLECULAR GENETICS OF EUKARYOTES

No.	Course Outcome (Cos): After completion of this course, the students will be able to	Pos &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	To understand the genetics of eukaryotes at molecular level	PO1& PS01	12	R
CO2	To know about the origin and mechanisms involved in DNA replication	PO1& PS01	12	R
CO3	To understand the mechanism involved in transcription	PO1& PS01	12	R
CO4	To understand the mechanism involved in translation	PO1& PS01	12	R
CO5	To obtain knowledge on genetics of cancer	PO1& PS01	6	R
CO6	To understand the knowledge on molecular level of cancer	PO1& PS01	6	R

UNIT I: CHROMOSOMAL ORGANIZATION LECTURE HOURS: 12

Chromosomal organization - Packaging ratio, nucleosome, DNA- Protein complex,core DNA ,Linker DNA, Histones, **Chromatin** - Mitosis, centromere, cell division,Euchromatin and heterochromatin ,chromosome banding - Active DNA,Inactive DNA, Constitutive heterochromatin,Facultative heterochromatin, **Centromere** - Simple-sequence DNA ,chromosomes , spindle microtubules , mitosis, **Mitochontrial DNA** - Crista junctions,synthesize ATP,cristae and inner membrane ,matrix, tRNA genes. ND1, ND2, NADHCoQ reductase complex.**Mutations In Mitochondrial DNA for disease** - Mutant , wild-type mtDNAs , cell type,heteroplasmy,mammalian somatic or germ-line cell division,chronic progressive external ophthalmoplegia and Kearns-Sayre syndrome,"ragged" muscle fibers, **Activity: MITOCHONDRIAL DNA MUTATIONS and DISEASE** - mt DNA ,mitochondrial DNA mutations, clinical manifestations, aging and cancer.

UNIT II: DNA REPLICATION LECTURE HOURS: 12

Dispersive, Conservative and Semiconservative mode of Replication - Types and Evidences to prove DNA Replication is Semiiconservative, **DNA Replication** - Definition and Replication process of eukaryotes, **Telomere and telomerase** - chromosomes,simple repeat, quartets, nucleo protein enzyme,essential for survival, **Transposons in eukaryotes** - Mobile DNA elements,Retrotransposons,terminal repeats (LTRs),evolution,gene duplications,exon shuffling, **Alu sequence** - repetitive DNA sequences,Alu probe,human DNA hybridizes,7SL RNA, a component of the signal-recognition particle, **SINEs and LINES** - Repeated sequences,protozoans, insects, and plants, genomes mammals. SINEs mammalian DNA,open reading frame ORF1 and ORF2 proteins,L1- encoded proteins, **Activity: MOBILE DNA (Eukaryotic Transposable Elements)** - transposable elements in Corn, Yeast, Drosophila,Human retrotransposons.

UNIT III: TRANSCRIPTION LECTURE HOURS: 12

RNA Polymerase II and Transcription factors - TFiiX initiate transcription, short concervered sequence, TATA Box, A.T rich octamer, DPE ,Promoter, trans acting factors, basal factors, activators, response elements, co activators,RNA polymerse, **Regulation of transcription**

- Control of gene expression,DNA,chromatin,RNA polymerase, cis acting regulatory sequences, lac operator, **CpG island** - CG-rich region,Promoter, transcription, DNA methylation, poly comb, **Molecular mechanism** - Capping,Splicing,Addition of poly(A) tail ,RNA editing,mRNA Stability,Translocation,Strand separation, Nucleotide selection,Promoter recognition, abortive initiation and promoter clearance,**Post transcriptional gene control** - microRNA mediated regulation, mRNA,RNA-induced silencing complex RNA polymerase I introns, **Processing of pre mRNA, RNA editing** - tRNA,rRNA , mRNA or miRNA ,plastids Editing by insertion or deletion ,Editing by deamination, C-U editing, A-I editing ,RNA editing in plant, mitochondria and plastids, **Activity I: Difference between prokaryotic and Eukaryotic transcription** - RNA Polymerase, Transcription factors, promoter regions, genome size.

UNIT IV: TRANSLATION **LECTURE HOURS: 12**

Translational mechanisms,tRNA,Ribosomes,Genetic code and features - Polypeptide, mRNA, ribosome, initiation, elongation, termination,start codon, methionine, open reading frame, stop codon,Initiation, elongation,termination,Composition,structure ,functional aspects,RNA polymerase III, Cleavage and Base Modification.**Regulation,Glycosylation,Protein cleavage** - Signal induced protein cleavage, asparagine, serine, and threonine, modification, addition and processing of carbohydrates, **Protein phosphorylation,Attachment of lipids** - Post translational modification,mechanisms for regulating protein activity, Protein kinases c, Phosphatases Activation of all cellsurface receptors, **Protein degradation & Ubiquitin** - Cytosolic proteins, proteasomes, ubiquitin-conjugating enzyme, ubiquitin ligase (E3),activating enzyme,conjucating enzyme. induced by SOCS proteins,regulating mitotic event, Proteasome , Core proteins, regulatory (cap) proteins Cytoplasm, **Activity: Translation mechanism in Eukaryotes** - initiation, elongation and termination

UNIT V: CANCER GENETICS AND DEVELOPMENTAL GENETICS

LECTURE HOURS: 12

Onco genes - Chromosome rearrangements, gene duplication,immortalization,transformation, metastasis, retroviral onco genes,oncogenecity,growth factor receptor gene, **Anti oncogenes** - p53 as an anti-oncogene, binds to promoters,binds to telomeres,activates the GADD45 repair proteinactivated by modifications of amino acids, **BRCA genes** - Genetic testing,produce tumor suppressor proteins,inherited mutation, female breast and ovarian cancer, **Colorectal cancer genes as model** - Inherited gene mutation, availability of precursor adenoma lesions and the existence of several clear-cut familial inherited susceptibilities, Wnt pathway, **Molecular approach to cancer** - oncogenomics,Mutation in human cancer,molecular cytogenetics, SNPs and functional polymorphisms in cancer, **Activity: Cancer genetics** - collection of information , diagnosis, treatment, molecular diagnosis.

Text Books :

T1. Molecular Cell Biology, Edition:4th W.H Freeman & Co, LodishH(2000)
T2. Molecular Cell Biology, Edition:5th, W.H Freeman & co, LodishH(2003)

Reference Books:

R1. GENES VIII, Edition:I, Peason Prentice Hal, BenjaminLewin(2004

M-III INTERMEDIARY METABOLISM

No.	Course Outcome (Cos): After completion of this course, the students will be able to	Pos &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	To enable Students to understand about the essential metabolic functions of the human organism as well as the molecular & biochemical basis of human diseases through analysis of the mechanisms of production, consumption and storage of energy	PO1& PS01	12	R,A, U, An, C
CO2	Understand the oxidation of carbohydrates takes place in the living system	PO1& PS01	12	R,A, U, An, C
CO3	To enable Students to understand about the relationships between fatty acids from our diet & metabolic processes.	PO1& PS01	6	R,A, U, An, C
CO4	To provide the Knowledge of the fundamental energetics & chemical logic of biochemical processes. To describe what happens in fatty acid oxidation and synthesis as well as in ketogenesis	PO1& PS01	6	R,A, U, An, C
CO5	Remember the degradation pathway of amino acids and proteins,	PO1& PS01	12	R,A, U, An, C
CO6	To enable the students to keep the key concepts about the biosynthesis, metabolsim and regulation of nucleic acids	PO1& PS01	12	R,A, U, An, C

UNIT I: INTRODUCTION TO INTERMEDIARY METABOLISM

LECTURE HOURS: 12

Anabolic, catabolic, amphibolic pathways; localization of pathways in the cell - Synthesis and degradation of organic compounds and its locations, **Biological oxidation- Redox potential; enzymes involved in oxidation and reduction** - Reactions catalyzed by dehydrogenases, oxidases, peroxidases and oxygenases; removing of H2 O2 from the biologic system, **Macroergic compounds; Respiratory chain- Oxidative phosphorylation** - Steps involved in oxidation and phosporylation, **TCA Cycle** - Location, pathway and explanation, **Activity- Chart on uncoupler comopund in oxidative phosphorylation** - Prepare a chart on recently identified uncoupler compounds of oxidative phosphorylation and to find and elucidate their structure and function.

UNIT II: CARBOHYDRATE METABOLISM LECTURE HOURS: 12

Over view of glycolysis - Reactions, intermediates, enzymes and coenzymes in glycolysis, coupling of glycolysis with other pathways, Glycolysis in erythrocytes, **Gluconeogenesis- Introduction to gluconeogenesis** - Localization, Non carbohydrate sources, Pathways and barriers, **Pentose phosphate pathway- Synthesis of pentose phosphate pathway** - Location, Pathway and Importance of HMP shunt, **Metabolism of**

glycogen- Glycogenesis and Glycogenolysis - Location, pathway of glycogenesis and glycogenolysis, **Uronic acid pathway- Metabolism of uronic acid pathways** - Location, pathway and explanation, **Activity- Working model on glycolysis** - Prepare a working model on glycolysis pathway using recyclable materials.

UNIT III: FATTY ACID METABOLISM LECTURE HOURS: 12

Biosynthesis of FA - Location, Production of acetyl CoA and NADPH, Conversion of acetyl CoA to malonyl CoA and Reactions of fatty acid synthase complex, **Oxidation of fatty acids** - a, ß and ? fatty acid oxidation, **Ketogenesis** - Ketone bodies and its synthesis, **Cholesterol metabolism- Cholesterol biosynthesis** - Location and synthetic pathway, **Degradation of Cholesterol** - Synthesis of bile acids, steroid hormone, vit D, **Activity- Collection of recently published articles** - Collect the informations about hormonal imbalances in human from recently published articles and to glue it on charts.

UNIT IV: PROTEIN AND AMINO ACID METABOLISM LECTURE HOURS: 12

General Pathway - Removal of amino group, Fate of amino group and Fate of carbon skeleton, **Catabolism of amino acid, Catabolism of amino acids** - Glycine, Tyrosine and Phenyl alanine, Tryptophan and Methionine, **Activity- Prepare an album for essential aminoacid containing food items** - Findout the three recent articles that denote food items containing high quantity of essential aminoacid and prepare it as an album followed by exhibitory the same to public.

UNIT V: METABOLISM OF NUCLEOTIDES LECTURE HOURS: 12

Synthesis of Purine - Salvage and De novo pathway of purine, **Synthesis of Pyrimidine** - Salvage and De novo pathway of pyrimidine, **Catabolism of Purine** - Catabolic pathway of purine, **Catabolism of Pyrimidine** - Catabolic pathway of pyrimidine, **Activity- Case study** - Case studies on people who are suffering from heriditary disorders.

Text Books:

T1.Biochemistry, Edition:II Arunaba Sen , U. Sathyanarayana (2002).

Reference Books:

R1 Biochemistry, Edition:III, John Wiley and Sons Inc, New York, Voet, D.J., Voet, J.G and Pratt, C.W (2004)

R2 Lehninger Principals of Biochemistry, Edition:IV, Worth Publishers, New York, Nelson, D.L and Cox, M.M (2008)

R3 Biochemistry, Edition:VII, Belmont CA, USA, Cambell, M.K and Farrell, S.O (2012)

M-IV IMMUNOTECHNOLOGY

No	Course Outcome (Cos): After completion of this course, the students will be able to	POs &PSOs	Cl.Ses	CL
CO1	Discuss the mechanism of immune system of our body	PO1 & PSO1	12	U
CO2	Explain the structure, functions and properties of immune cells	PO1 & PSO1	12	U
CO3	Describe the mechanism and process of transplantation immunity and hypersensitivity reactions	PO1 & PSO1	12	U
CO4	Explain the causes of primary and secondary immunodeiciency, mechanism of autoimmune disorders and immunity against bacteria, viruses and protozoa	PO1 & PSO1	12	U
CO5	Describe the production methods of hybridoma technology and its applications	PO1 & PSO1	6	U
CO6	Explain the functions of stem cell therapy and production of immunological vaccines	PO1 & PSO1	6	U

UNIT I **LECTURE HOURS: 12**

History of Immunology- History and Scope of Immunology - Historical Perspective, Early studies revealed that humoral and cellular components of the immune system, Early theories of Antibody Antigen Interaction – Selective theories and Clonal section theory, **Types of Immunity-** Innate Immunity - Definition, non-specific defense mechanism, types of barriers – anatomic, physiologic, endocytic and phagocytic barriers, macrophages and neutrophils **Lymphoid organs-** Primary Lymphoid organs - Site of origin, functions, Types of Lymphoid organs – primary (thymus and bone marrow)- origin, structure & function, Secondary & Tertiary Lymphoid organs - Secondary (lymph node and spleen, MALT and GALT) loose clusters of follicles,Peyer's patches of the intestine, and CALT- origin, structure & function, **Hematopoietic system** - Hematopoiesis –Origin, differentiation and developmental stages and different types of blood cells, B cells, role of dendritic cells – antigen, Type of immune cells - Definition, T cells, B cells, Natural killer cells, sub type of natural killer cells, NK1-T cells, receptors, **Antigens and Immunoglobulins-** Immunogenicity - Immunogenecity Vs antigenecity, factors that influence antigenecity, Epitopes, Haptens and the study of antigenecity, pattern recognition receptors.

Immunoglobulins - Structure of antibodies, antibody mediated effector functions, classes and biological activity, antigenic determinants on immunoglobulins , B cell receptor & immunoglobulin super family, Idiotypic Network, Antigen antibody interactions - Antigenic determinant – structure, functions and types Isotypic, Allotypic and Idiotypic. Principles and applications-strength of antigen antibody interactions , cross reactivity, precipitation reactions

agglutination reactions, Radio immunoassay, ELISA, Western blotting,Immunoprecipitation and Immunofluorescence, **Activity-** ELISA - Prepare a working model of ELISA.

UNIT II **LECTURE HOURS: 12**

Origin of B and T cells- Ontogeny of B and T cells - Origin of Hematopoietic Stem Cells, immunological status of the newborn, Maternal IgG in the Newborn, Maternal/Fetal Interactions, T and B cells receptors - T cell receptor- structure, types, origin and function (T-cell membrane), activation, differentiation, target source, effect of recognition. B cell receptor – structure, types, origin, function, activation, differentiation, maturation , **Major Histocompatibility complex-** MHC class I , II and III molecules - Structure-Three extra cellular domains, ß 2 micro globulins, HLA complex in human and mice, structure of class I molecules, exogenous processed antigens to CD 8 T cells .Exogenous processed antigens to CD 4 T cells class III molecules- diverse group of proteins, regulation of MHC expression.
MHC restriction and antigen processing - Self –MHC Restriction of T-cells, Role of Antigen presenting cells, Cytosolic and Endocytic pathway, Presentation of non-peptide antigens. Antigen Processing and Presentation, Antigen Presenting Cells, Presentation of Super antigens, Role of cytokines - Properties of cytokines receptors, cytokine antagonists, cytokine secretion by TH 1 and TH 2 sub cells, cytokine related diseases, therapeutic uses of cytokines and their receptors, cytokines in hematopoiesis. Properties of cytokine receptors, **Complement systems-** Classical pathway & Alternative pathway - Functions of complement, components, complement activation and regulation, biological consequences of complement activation, complement deficiency, **Genetic control of immune response -** Genetic Influences of Immune Responsiveness and Regulation - HLA associated autoimmune diseases, Reiters Syndrome, MHC Associated Diseases, **Activity-** Prepare a chart on complementary activation pathway - Classical pathway, lectin pathway, alternative pathway, lytic pathway.

UNIT III **LECTURE HOURS: 12**

T Cell mediated cytotoxicity- Cytotoxic T-cells - Cytotoxic T cells- properties, functions, mechanism of effectors cells, First phase &Second Phase-activation & differentiation.Cell death, mechanism – Perforin, Granzyme, Fas/FasL pathway, **Transplantation Immmunology-** Transplantation Immunity – Immunologic Basis of Graft Rejection, Clinical Manifestations of graft Rejection, General Therapy, Specific Immunosuppressive Theory, Immune tolerance to Allograft, Clinical transplantation, Graft Rejection, Role of T lymphocytes in rejection - Types of Graft – Autograft, Isograft, Allograft and Xenograft. Mechanism – hyper acute and acute rejection, tissue damage.
Organ transplantation - Kidney and Blood Transplantation, **Hypersensitivity reactions**
Types and Mechanism - Hypersensitivity Reactions - Type I - Allergens – IgE, mast cells, basophils, histamine, defence role of IgE antibodies. Type II-Hemolytic disease, damage of target tissues. Type III- Immune complex, inflammatory response, experimental models, tissue damage. Type IV –three variants-contact tuberculin, granulomatous, **Activity**
Success stories of transplantation - Renal, heart, lung, liver, bone marrow, kidney & blood transplantation.

UNIT IV **LECTURE HOURS: 12**

Immunodeficiency- Primary and Secondary Immunodeficiency - Immunodeficiency, Primary immunodeficiency -primary antibody deficiency, SCID Secondary Immunodeficiency - Causes and results, infectious diseases, Immunological tolerance and Immunosuppression - Ways of inducing tolerance, tolerance induction in early development, mechanism, Autoimmune disorders - Autoimmune disorders, mechanism of tissue damage,

classification - organ specific and systemic control of autoimmune disorders. Autoimmune antibodies, mechanism and types, Treatment of Autoimmune disorders, Immunity against bacteria - Mechanism, structure, bacterial recognition pathways, antigen-specific mechanism. Phagocytes, macrophages - phagocyte mediated killing, tissue damage, antibacterial immunity, Viruses and protozoa - Virus- Mechanism, Innate immunity, adaptive immune response, strategies, viral antigen, tissue damage. Protozoa - parasitic infections, innate immune responses, effector cells- role, mechanism, functions, **Activity-** Prepare a photo album, projecting the deleterious effects of autoimmunity. - Effects of mutiple organ system and gender difference in autoimmune disease.

UNIT V **LECTURE HOURS: 12**

Hybridoma techniques- Monoclonal antibody - Production and applications T cell cloning and their role in vaccine production - Selection of strains, growth of microorganisms, Inactivation, Formulation of Vaccine, **Stem cell therapy-** Stem cell therapy - Stem cell types - somatic stem cells, adult stem cells, embryonic stem cells, potential uses of adult stem cells.Hematopoietic stem cells, therapeutic cloning, **Recombinant vaccine-** Recombinant Vaccine - Recombinant vector vaccines- Production and applications, **Activity-** Awareness programme on vaccination for rural folks in and around sulur. - Polio, MMR, Hep A, Hep B, flu, Rotovirus (RV), Tdap.

Text Books:

T1. Kuby Immunology, Edition:6, Freeman and Compan, Thomas.J.Kindt, Barbara.S.Orsborne, Richard.A.Gold(2009)
T2. Immunology, Edition:7, Elsevier, David B Roth and David Male and Ivan Roitt and Jonathan Brostoff(2006)
T3. Immunobiology, Edition:5, Garland Science, Janeway, C. A., Jr. and P. Travers (1994)

MP-I LAB IN ENZYMOLOGY, IMMUNOTECHNOLOGY AND MOLECULAR GENETICS

ENZYMOLOGY

1. Isolation of Amylase, Cellulase, Protease and Lipase producing microorganism from soil
2. Estimation of extracellular enzymes from bacteria by quanttitative method
3. Determination of Km and Vmax of alpha amylase
4. Determination of Molecular weight of the protein by SDS-PAGE

IMMUNOTECHNOLOGY

5. Immunoelectrophoresis
6. Rocket immuno electrophoresis
7. ELISA- Dot and Sandwich
8. Immunodiffusion
9. Western Blotting
10 Isolation of Ig Y from egg yolk

MOLECULAR GENETICS

11. Isolation of DNA from human blood
12.Restriction mapping for human DNA- RFLP
13. RAPD
14.Isolation of polythene chromosome from salivary gland of Drosophlia melanogaster
15. Gene induction: Beta galactosidase in *E.coli*.
16. AMES Test

Text Books:

T1.Lab Manual in Biochemistry, Immunology and Biotechnology, Edition:2, TATA Mc GRAW HILL, ArchanaAyyagari and Arti Nigam,(2007)
T2. Practical enzymology | Edition: 2nd completely revised, Wiley Blackwell.

M-V INTRODUCTION TO CLINICAL TRIALS

No.	Course Outcome (Cos): After completion of this course, the students will be able to	Pos &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	Learn the basics of clinical trials	PO1& PS01	12	R
CO2	Understand the good clinical practice and the role of IRB	PO1& PS01	12	R
CO3	Learn about clinical trial protocols CO4	PO1& PS01	12	R
CO4	Describe the Informed consent and Role of IRB/IEC	PO1& PS01	12	R
CO5	Guidelines of Case Report Form	PO1& PS01	6	R
CO6	Design of Case Report Form	PO1& PS01	6	R

UNIT I: BASIC IN CLINICAL TRIALS **LECTURE HOURS: 12**

Introduction to Clinical Research - New drug, licensing authority rule 21, trial site, trial investigators and protocol amendments, **Responsibilities of Sponsor**: Maintaining quality assurance, data, document, report and serious adverse drug, **Responsibilities of the Investigators**: - GCP guidelines, standard operating procedure, subjects participation and medical care, **Informed Consent**: - Study subject, patient information sheet, informed consent form, **Responsibilities of the Ethics Committee** - Trial protocol, hierarchical structure, intervals and monitoring internal audit. **BASIC CLINICAL TRIAL METHODOLOGY: Trial Design-Blinded Trial** - Type of intervention, study population characteristics, investigational medicinal product, to avoid bias and single, double blind trial, **Superiority Trial** - Scientifically, efficacy, active control treatment in trials and choice of comparator, **Randomized Trials**: - Placebo, factorial design, stratification and open-label, **Clinical Trials and its Phases: Phase I &Phase II** : - Human pharmacology- estimation of safety tolerability, maximum tolerated dose, **Phase III &Phase IV**: - Conformation of therapeutics benefits, licensing authority and post marketing trials, **Activity- Clinical trials registry India** - How to pick the data from clinical trials registry India.

UNIT II: GOOD CLINICAL PRACTICE **LECTURE HOURS: 12**

Investigational New Drug Application 21 CFR 312-General Provisions - General Provisions, Scope, Applicability, Definitions and interpretations, Labeling of an investigational new drug and Promotion of investigational drugs, **Investigational New Drug Application** - Requirement for an IND, Phases of an investigation, General principles of the IND submission, Information amendments and IND safety reporting, **Administrative Actions Responsibilities of Sponsors and Investigators**: - General responsibilities of sponsors, Transfer of obligations to a contract research organization and Selecting investigators and monitors, **Investigator's Obligations: Institutional Review Boards 21 CFR 56- Definitions** - Scope, Definition, **IRB review IRB requirement Registration** - IRB requirement, Waiver of IRB requirement Registration and IRB membership, **Activity: Sponsors** - Listout the sponsors for clinical trials in India

UNIT III:CLINICAL TRIAL PROTOCOL LECTURE HOURS: 12

Trial Objectives and Purpose - General Information and Background Information, **Trial Design** - Specific statement, description of the type/design, Randomization, Blinding, subject participation, stopping rules and investigational product, **Treatment of Subjects Assessment of Efficacy Assessment of Safety** - Product, the dose, the dosing schedule, the safety parameters, route/mode and Medication/treatment permitted, **Selection and withdrawal of Subject:** - Subject inclusion criteria, Subject exclusion criteria, Subject withdrawal criteria, withdraw subjects and follow-up for subjects, **Ethical & Safety Considerations: Ethical Principle** - Principles of essentiality, voluntariness, privacy, confidentiality, precaution , risk minimization, **Ethics Committee** - Sponsor, ethics committee, informed consent and international guidelines for biomedical research, **Basic responsibilities** - IEC, membership requirement, quorum requirement and research participants, **Review procedures** - Ethical review and submission application, **Record keeping** - Composition of IEC, curriculum vitae, standard operating procedure, **Informed consent of subject** - Investigator, legal representative, impartial witness and essential information for prospective research on subjects, **Decision making process:** - Broad consensus, proposal of review, negative review, interim review and positive decision, **Special consideration:** - Biomedical research, research, children, lactating women and vulnerable subjects, **Activity: Preparation of question** - Prepare the pre screening questionnaire for clinical trials.

UNIT IV: INFORMED CONSENT LECTURE HOURS:12

Overview of informed consent - Subject, authorized representative, process and documentation, **Informed consent in exempt research** - Regulatory requirements, 45 CFR 46 and Belmont Report, **Documentation of informed consent** - The subject's legal representative signs and impartial witness, **Information that must be provided to subjects:** - Basic Elements, Additional Elements, Recruitment and Exculpatory Language, **Roles and Responsibilities IRB / IEC- Composition, Functions** - Safeguard the rights, Trial protocol(s)/amendment(s), qualifications of the investigator, review, paragraph, protocol and information regarding payment, **Operations Procedures and Records:** - Determining its composition, Scheduling, Conducting initial, Deviations from, relevant records, **Activity: Consent form** - Prepare a model consent form.

UNIT V: CASE REPORT FORM LECTURE HOURS: 12

Introduction - Principal investigator, data management, case report form templates and chemo preventive trials, **Header/Identifier Information** - NCI Contract Number and Study Title, Subject Initials, Study Center Code, Visit Number and Visit Date, **Guidelines for CRAs- Completing CRFs & General instructions for completing forms:** - Clinical trial book, laboratory results, ink pen, identical, missing, unknown data, Assigned member, signed the Signature Form completed within one week, **Numeric Data Entry** - Date ,time and numbers version date and subject number, **General Case Report Forms**- Instructions for Design, **P.I. Verification Form** - Principal Investigator subject study completion and PI signature, **Subject Enrollment Form** - Demographic information Date of Birth, Gender, Race, Weight and Height, Subject Number, Date, Subject Enrolled and Drug Start Date, **Eligibility Form** - Inclusion Criteria and Exclusion Criteria, **Medical History** - Normal box, Body Systems and Record, **Clinical Laboratory Data** - Laboratory tests, Insert the appropriate units, multi-center studies, clinical significance, Agent Levels, Date of Collection and Fasting, **Concomitant Medication** - Date of the visit, brand name, one medication per section, Visit Dates, NONE box, Signs, Symptoms, Start and Stop Dates, Event Recovery Status, Continuing Adverse Events, Relationship to Study Drug and Toxicity Graden, month

and year of the Start and Stop Dates, **Subject Randomization Form:** - Date Run-in Started and Date Run-in Ended, Date Subject Randomized and Subject Randomization Code, **Physical Examination** - Vital Signs, Performance Status, Body System, **Study Specific Case Report Forms: Instructions for Design**- Biomarker Forms - Study-specific forms, biomarker endpoints, templates, Baseline biomarker and Biopsy Specimen Number, **Activity: Interpretation of result** - How to interpret your data followed on documentation.

Text Books :

T1. Good Clinical Practices for Clinical Research in India, Consortium, Edition:1, Clinical Research PVT Ltd (2010).

T2 - Schedule Y(Ammended Version) – CDSCO, Edition:1, Consortium, Clinical Research PVT Ltd, (2010).

T3 -Training and Resources in Research Ethics Evaluation, Good Clinical Practice, Edition:1 Module 3.2, TRREE, Module GCP Version 1.0 2012-08, (2012)

T4 -History & Regulations, Department of Rehabilitation and Mental Health Counseling | Edition:1, College of Arts and Sciences University of South F, (2000)

Reference Books:

R1- Informed Consent, Edition:1, Duke University, 2008, Duke University, Lorna Hicks(2008)

R2- Guidelines for Designing and Completing Case reports Forms, Edition:0, 4/98, rev. 7/99, rev. 3/00 DCP Internet Supplement, (2010).

SEMESTER-II

M-VI CHEMISTRY OF PROTEINS AND PROTEIN ENGINEERING

No.	Course Outcome (Cos): After completion of this course, the students will be able to	Pos &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	Describe the structure, properties of aminoacids and to discuss about the classification and levels of structural confirmation of proteins	PO1& PS01	12	U
CO2	Predict the protein conformation by Ramachandran plot and to explain the domain and motifs involved in DNA binding.	PO1& PS01	6	U
CO3	Express the physical and chemical agents involved in protein denaturation and to discuss the proteins involved in folding mechanism	PO1& PS01	6	U
CO4	Describe the extraction, purification and separation techniques involved in proteins and to discuss the methods for the determination of aminoacid sequences and chemical synthesis of peptides and proteins.	PO1& PS01	12	R, U, A, C
CO5	Explain the process of oligonucleotide directed mutagenesis with M13DNA and plasmid DNA, PCR amplified oligonucleotide - Directed mutagenesis and Random mutagenesis	PO1& PS01	12	R, U, A, C
CO6	Discuss the application of protein engineering in recombinant protein for industrial uses, food and detergent, medical uses and waste water treatment process.	PO1& PS01	12	R, U, A, C

UNIT I: PROTEIN STRUCTURE **LECTURE HOURS: 12**

Amino acids - General structure, Classification and function, **Properties of amino acids** - Zwitter ion, ampholytes, physical and chemical properties, **Peptides and Proteins** - Definition, Oligopeptides, Polypeptides, Oligomeric and Protomers, **Hierarchial organization of protein structures** - Introduction to levels of protein, **Primary level** - Sequence of amino acids, **Secondary level** - Alpha helix and beta sheets(Collagen and Keratin), **Tertiary level** - Three dimensional arrangement of all atoms in protein (Myoglobulin and IgG), **Quarternary level** - Proteins have multiple polypeptide chains (Hemoglobin), **Acitivity** - Prepare a model on protein architecture.

UNIT II: STRUCTURE BIOLOGY OF PROTEIN **LECTURE HOURS: 12**

Ramachandran Map and Protein conformation - Conformations of the main chain of a protein molecule, **DNA binding proteins** - Domains and Motifs- HTH, Leucine Zipper, Zinc finger motifs, Greek Key motifs and forces governing protein architecture, **Hydrophilicity plot of protein** - Quantitative analysis of the degree of hydrophobicity or

hydrophilicity of amino acids of a protein, **Structure of chaperones and chaperonins** - Molecular folding proteins- Hsp70 and GroEL/GroES, **Protein Denaturation and Folding** - Disorganisation of the native protein molecule, physical agent, chemical agent and folding of protein, **Activity** - Prepare a model on gene binding proteins.

UNIT III: PROTEIN ANALYTIC TECHNIQUES LECTURE HOURS: 12

Protein extraction - Differential centrifugation and fractionation, **Purification of proteins** - Dialysis, Column chromatography, ion exchange chromatography, size exclusion chromatography and affinity chromatography, **Protein separation** - Electrophoresis, iso electrofocussing, and two dimensional electrophoresis, **Determination of amino acid sequences** - Determination of amino acid, Degradation of protein and determination of amino acid- Sanger's reagent, Edman's reagent and sequenator, **Chemical synthesis of peptides and proteins** - Synthesis of peptides on an insoluble polymer support, **Activity** - Prepare a chart on various protein separation techniques.

UNIT IV: DIRECTED MUTAGENESIS IN PROTEIN LECTURE HOURS: 12

Oligonucleotide directed mutagenesis with M13 DNA - Oligonucleotide, Klenow fragment, T4 DNA , Ligase, Transformation, DNA hybridization, M13 Bacteriophage, Site specific mutation, **Oligonucleotide directed mutagenesis with plasmid DNA** - Double stranded plasmid DNA , Single stranded circular DNA,T4 DNA ligase, DNA hybridization, Transformants, Target gene, **PCR -Amplified oligonucleotide- Directed mutagenesis** - PCR Oligonucleotide primers, Hybridization, dut ung system, **Random mutagenesis with degenerate oligonucleotide primers** - Target proteins, degenerate oligonucleotides, restriction endonuclease, **Activity** - Chart work on Directed mutagenesis.

UNIT V: APPLICATIONS OF PROTEIN ENGINEERING LECTURE HOURS: 12

Applications - Food and detergent, Medical, Biopolymer production, Nano biotechnology application, Application with redox proteins and enzymes, Application with various industrially important enzymes, other new application, **Recombinant protein for industrial uses: Utilization of Pichia Pastoris expression system** - Recombinant protein for industrial use, Pichia Pastoris an expression system ,Animal feed additive, Phytase from E.Coli, Phytase from Aspergillus fumigates, Gelatin Industry, Waste water treatment and Bleaching, Laccase from Trametes versicolor, Laccase from Pleuotus sajor-caju, Antifreeze, Lytic enzyme, **Activity** - Collection of articles on protein applications.

Text Books:

T1.T1.Biochemistry, Edition:II Arunaba Sen , U. Sathyanarayana (2002)

Reference Books:

R1. Molecular Biotechnology, Edition:3 rd, ASM press, Bernard R.Glick and Jack J.Pasternak(2006).

R2. Principles of Biochemistry, Edition:4 th, W.H.Freeman and company, David Nelson and Michael M.Cox(2007).

R3. Protein Engineering, Edition:II, InTech, Pravin Kaumaya (2012).

M-VI CHEMISTRY OF PROTEINS AND PROTEIN ENGINEERING

No.	Course Outcome (Cos):On completion of this course, the students will be able to	POs & PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	Describe the structure, properties and classification of proteins and amino acids .	PO1& PS01	12	R, U
CO2	Learn the structure and construction of proteins	PO1& PS01	12	R, U
CO3	Analyze the techniques involved in protein Engineering.	PO1& PS01	12	R, U
CO4	Acquire the knowledge on experimental methods of protein engineering	PO1& PS01	12	U
CO5	Explain the application of Protein engineering in various fields,	PO1& PS01	6	U, A
CO6	Evaluation studies of Vaccine Applications and Drug discovery	PO1& PS01	6	U, A

UNIT I: PROTEIN STRUCTURE LECTURE HOURS: 12

Amino acids - General structure, Classification, Physicochemical properties and function of amino acids. **Proteins and Peptides** –Classifications and Properties. **Hierarchical organization of protein structures** -, **Primary level**, **Secondary level**, **Tertiary level** and **Quaternary level**). **DNA binding proteins** - Domains and Motifs- HTH, Leucine Zipper, Zinc finger motifs, Greek Key motifs and forces governing protein architecture. **Structure of chaperones and chaperonins** - Molecular folding proteins- Hsp70 and GroEL/GroES, **Activity** - Prepare a still model on protein architecture.

UNIT II: INTRODUCTION TO PROTEIN ENGINEERING LECTURE HOURS: 12

Protein engineering – Definition, Methods and Features or characteristics of proteins that can be engineered as pH, temperature and amino acid sequence, aggregation. Forces stabilizing proteins – Van der waals, electrostatic, hydrogen bonding and weakly polar interactions, hydrophobic effects; Entropy – enthalpy compensation. **Protein Denaturation and Folding** - Disorganization of the native protein molecule by physical and chemical agent. Protein Folding. **Activity** - Prepare a Flow chart of protein engineering.

UNIT III: ANALYTIC TECHNIQUES USED FOR PROTEIN ENGINEERING LECTURE HOURS: 12

Protein extraction - Differential centrifugation and fractionation, **Purification of proteins** - Dialysis, Column chromatography, ion exchange chromatography, size exclusion chromatography and affinity chromatography, **Protein separation** - Electrophoresis, Iso electro focusing, and two dimensional electrophoresis. **Methods of measuring stability of a protein**; Spectroscopic methods to study physicochemical properties of proteins: UV, CD; Fluorescence; ORD. **Hydrophilicity plot of protein** - Quantitative analysis of the degree of hydrophobicity or hydrophilicity of amino acids of a protein. **NMR spectroscopy** – emphasis

on parameters that can be measured/obtained from NMR and their interpretation. **Determination of amino acid sequences** - Determination of amino acid- Sanger's reagent, Edman's reagent and sequenator. **Chemical synthesis of peptides and proteins** - Synthesis of peptides on an insoluble polymer support. **Activity** - Prepare a chart on various protein separation techniques.

UNIT IV: EXPERIMENTAL AND COMPUTATIONAL APPROACHES TO PROTEIN ENGINEERING LECTURE HOURS: 12

Experimental methods of protein engineering: Optimization and high throughput screening methodologies like GigaMetrix, High throughput microplate screens etc. **Oligonucleotide directed mutagenesis with M13 DNA** - Site specific mutation, **Oligonucleotide directed mutagenesis with plasmid DNA** - Target gene, **PCR -Amplified oligonucleotide-** Directed mutagenesis - **Random mutagenesis with degenerate oligonucleotide primers** - Target proteins, degenerate oligonucleotides. **Computational approaches to protein engineering:** sequence and 3D structure analysis, Data mining, Ramachandran map, Protein design. **Activity** - Chart work on Directed mutagenesis

UNIT V: APPLICATIONS OF PROTEIN ENGINEERING LECTURE HOURS: 12

Applications - Food and detergent, Medical, Biopolymer production, Nano biotechnology application, Application with redox proteins and enzymes. Application with various industrially important enzymes. **Recombinant protein for industrial uses: Utilization of Pichia Pastoris expression system** - Recombinant protein for industrial use., Gelatin Industry, Waste water treatment and Bleaching. Engineering antibody affinity by yeast surface display; Applications to vaccines, Peptidomimetics and its use in drug discovery. Activity - Collection of articles on protein applications.

Text Books:

T1. Biochemistry, Edition: I Arunaba Sen , U. Sathyanarayana (2002)

Reference Books:

R1. Molecular Biotechnology, Edition:3 rd., ASM press, Bernard R. Glick and Jack J. Pasternak (2006).

R2. Structure in Protein Chemistry, 2nd Edition, Garland publishers. J Kyte; (2006).

R3. Protein Engineering Protocols, 1st Edition, Humana Press. Mueller

M-VII FERMENTATION AND INDUSTRIAL BIOTECHNOLOGY

No.	Course Outcome (COs): After completion of this course, the students will be able to	POs &PSOs	Cl. Ses	BLOOM'S TAXONOMY LEVEL
CO1	Recall the basis of fermentation technology	PO1& PSO1	12	U
CO2	Know the types of fermentation and fermenter used in industries	PO1& PSO1	12	U
CO3	Develop the knowledge on Upstream processing	PO1& PSO1	12	U
CO4	Learn the techniques involved in downstream processing of enzymes	PO1& PSO1	12	U
CO5	Describe the production of various industrial products	PO1& PS01	6	U
CO6	Understand the products of food technology	PO1& PSO1	6	U

UNIT I: Introduction to Fermentation Technology LECTURE HOURS: 12

History and milestones of fermentation technology, scope of fermentation technology. Isolation and screening of industrially important strains- primary and secondary screening. Strain improvement, mutation, selection of mutants, recombination – bacteria, fungi and actinomycetes, assay and fermented products. Fermentations- submerged solid state.

UNIT II: Fermenter: Design, Control and Monitor LECTURE HOURS: 12

Design of fermenter, Types – CSTR, Tower, jet loop, air lift fermenter, bubble column, packed bed. Fundamentals of process control and monitoring – on line and off line analysis, feedback control – pH, temperature, pressure, O_2 and CO_2 control, PID controller, computer aided control. Role of aeration and agitation.

UNIT III: Upstream Processing LECTURE HOURS: 12

Media formulation – Sterilization – Air and media sterilization. Microbial kinetics: batch, fed-batch and continuous cultures, phases of batch growth. Kinetics of cell growth, product formation, substrate utilization, product inhibition kinetics, yield concept and productivity.

UNIT IV: Down Stream Processing LECTURE HOURS: 12

Introduction, removal of microbial cells and solid matters, foam separation, precipitation, filtration, centrifugation, cell disruption. Solvent extraction-chromatographic separation-FPLC, HPLC, dialysis, distillation, crystallization. Effluent treatment. Fermentation products available in market.

UNIT V: Application of Fermentation And Inustrial Biotechnology

LECTURE HOURS: 12

Whole cell immobilization, protein immobilization and their industrial application. Industrial production of chemicals: alcohol, acids (citric, acetic and gluconic acid), solvents (glycerol, acetone and butanol), antibiotic (penicillin, streptomycin and tetracycline), amino acids (lysine and glutamic acid), Single cell protein, use of microbes in mineral beneficiation and oil recovery, probiotics and prebiotics.

Text Books:

T1. Industrial introduction to biochemical engineering, Edition: 2, TATA McGraw Hill Education, D G Rao (2010).

T2. Prescott & Dunn's Industrial Microbiology, Edition: 2, G. Reed, G. Reed (2009)

T3. Industrial Microbiology, Edition: 2, John Wiley & Sons, L.E.J.R. Casida (2019)

Reference Books:

R1. Principles of Fermentation Technology, Edition: 4, Books & Allied (P) Limited, Kolkata, Peter F. Stanbury (2010).

R2**.** Bioprocess Engineering Basic Concept**,** Prentice Hall International Services, 3rd Edition, 2017. Michael L. Shuler Fikret Karg.

M-VIII GENETIC ENGINEERING

No.	Course Outcome (Cos): After completion of this course, the students will be able to	Pos &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	To describe the learners with fundamentals of engineering tools principles in gene application and also to expose them to conventional as well as modern tools for genetic manipulation.	PO1& PS01	12	R
CO2	To explain the physical gene vector maps with emphasis to the active attributes along with their functions and also to discuss the salient features of different vectors and to design a typical gene cloning vector based on specific needs.	PO1& PS01	12	U
CO3	To illustrate the concept, design and applications of genomic library, cDNA library by giving special focus to its expression profile.	PO1& PS01	12	U
CO4	To explain the concept of phage display, site directed mutagenesis and protein engineering and their role in clinical diagrammatic as well as treatment.	PO1& PS01	12	U
CO5	To define gene therapy and to classify the types of gene therapy.	PO1& PS01	6	R/U
CO6	To apply various types of therapeutics based on the genetic diseases.	PO1& PS01	6	R/U

UNIT I: INTRODUCTION TO GENE MANIPULATION LECTURE HOURS: 12

Basic Techniques: Isolation and Purification of Nucleic Acids - Isolation of DNA & RNA, RNase inhibitors. **Agarose Gel Electrophoresis** - Agarose, factors influencing rate of migration. **Southern Blotting** - Southern setup & various methods of transfer. **Northern Blotting** - Hybridization & reaction setup.**Western Blotting** - SDS PAGE & Blotting. **PCR** - Principle, types and applications.**ENZYMOLOGY OF RECOMBINANT DNA - DNA Ligases** - Types of ligases, reaction mechanism & ligation strategies. **Topoisomerases & Gyrases** - Role in plasmid replication & inter connected diagram. **Activity** - Innovative/cost effective protocol development for nucleic acid/ protein isolation.

UNIT II: GENE CLONING VECTORS LECTURE HOURS: 12

Plasmids - Definition, properties, pBR322 & derivatives, **Bacteriophages** - Bacteriophage as cloning vehicle and its molecular biology and lambda vectors, **Phagemids** - Definition & Cloning,**Cosmids** - Construction & Cosmid cloning, **Artificial Chromosomes** - Cloning with high capacity vectors & four classic examples, **Mapping of DNA fragments & Map Construction** - Genetic & physical maps, markers, Restriction mapping & Hybridizations techniques,**DNA Sequencing** - Maxam Gilbert & Sanger dideoxy method, **Gene expression** - Transcription & Translation, **Cloning in E.Coli** - pBR322,pUC18 & Expression vectors. **CLONING IN ORGANISMS OTHER THAN E.COLI- Bacillus** - Cloning ,vectors & expression, **Streptomyces, Pseudomonas and Gene Transfer**

Techniques - Cloning ,vectors & expression, Physical & biological transfer. **Activity** - Commercial attractive vector study and report submission.

UNIT III: GENOME LIBRARY LECTURE HOURS: 12

Construction of Genomic Library - Isolation, vectors, ligation & selection. **ISOLATION AND CHARACTERIZATION OF GENE TRANSCRIPTS- Converting mRNA Transcripts into cDNA** - Synthesis of cDNA, **Screening Representative cDNA Libraries** - Selection strategies, **Functional Sequencing of cDNA Expression Libraries** - Cloning & expression libraries, **Using Cloned cDNA as a Reagent** - Vectors & Selection. **Nucleic Acid Microarray** - Definition, types, methodology & applications, **Activity** - Genomic / cDNA -New strategies.

UNIT IV: SITE DIRECTED MUTAGENESIS LECTURE HOURS: 12

Screening Recombinant Clones for Site Directed Mutagenesis - Types, techniques & selection, **Detection of Mutation by SSCP and Heteroduplex Analysis** - Differences in electrophoretic mobilities of wild type, mutant nucleic acids & Cleavage of heteroduplexes, **Phage Display** - Phage properties and Applications,**Accessing Molecular Genetic Information through the Internet** - Molecular Genetic information & world wide web, **Nucleic Acid Probes and their Role in Disease Diagnosis** - Introduction, technique-biotyping, protein, phage & chromatographic analysis, **Activity** - New products by protein engineering through directed mutagenesis.

UNIT V: GENE THERAPY LECTURE HOURS: 12

Different Strategies for Gene Therapy - Definition, types & Different strategies, **Therapeutics Based on Targeted Inhibition of Gene Expression and Mutation Correction Invivo** - Inhibition of DNA, RNA & Protein level(Mutant protein), **Triple Helix Therapeutics** - Formation of triple helix DNA, Molecular modeling, Limitations encountered in triple helix formation & Applications of triple helix DNA, **Antisense Oligonucleotide & Ribozymes** - Introduction, diagram & applications, **Gene Therapy for Inherited Diseases-ADA & FH** - Clinical Manifestation and Treatment, **Cystic Fibrosis & DMD** - Cftr gene, therapy for CF, DMD & diagnostics test, **Neoplastic Disorders and Infectious Diseases** - General principle, Cancer gene therapies, Gene therapy for infectious disorders & Gene transfer into tumor-infiltrating lymphocytes, **Somatic Cell Gene Therapy** - Definition, Approaches for gene therapy, **RNAi** - Discovery ,Cellular mechanism, Biological functions, applications (technological & Clinical), **Activity** - Recent successful stories in gene therapy.

Text Books:

T1.Genes & Genomes, Edition:1, University Science Books,Maxine Singer(1991).
T2. Human Molecular Genetics, Edition:Revised, Garland Science, Tom Strachan, Andrew Read (2010).
T3. Molecular cloning, Edition:3, CSHL Press, Sambrook and Russell(2001) .
T4. Text book of Biotechnology, Edition: 2, Panima publishing Corporation, and S.Chand and Dubey R (2009).

Reference Books:

R1. Genomes, Edition:1, Bios Scientific Company, T.A. Brown (1999).
R2. Principles of Gene Manipulation & Genomics, Edition:1, Black Well publishing, S.B.Primrose (2006).

M-IX GENOMICS AND PROTEOMICS

No.	Course Outcome (COs): After completion of this course, the students will be able to	POs &PSOs	Cl. Ses	BLOOM'S TAXONOMY LEVEL
CO1	Understand the basic methods of genomic, transcriptomic and proteomic analysis.	PO1& PSO1	12	R
CO2	Describe Gene mapping	PO1& PSO1	12	R
CO3	Gain the knowledge on Comparative and Functional Genomics	PO1& PSO1	12	U
CO4	Acquire the Extensive knowledge of various methodologies of next generation sequencing and metagenomics, and microarray technologies	PO1& PSO1	12	U
CO5	Learn Bioanalytical and Bioinformatics techniques for Proteomics studies.	PO1& PSO1	6	U
CO6	Learn the Microarray technique for gene expression study	PO1& PSO1	6	U, A

UNIT I: Basics of Genomics And Proteomics LECTURE HOURS: 12 `

Structure and organization of prokaryotic and eukaryotic genomes - nuclear, mitochondrial and chrloroplast; computational analysis of sequences- finding genes and regulatory region, Gene annotation. **Sequence Alignment** - Pairwise Sequence Alignment, Evolutionary Basis, Sequence Homology versus Sequence Similarity, **Multiple Sequence Alignment** - Scoring function, Exhaustive Algorithms and Heuristic Algorithms. Genetic variations, deleterious mutation; Introduction to molecular phylogeny and evolution. **Activity** - List out the current published sequence alignment databases.

UNIT II: Gene Mapping LECTURE HOURS: 12

Genetic Techniques - Cross breeding and pedigree analysis to construct genome maps. Next generation sequencing, Automated DNA sequencing, DNA markers - RFLP, SSLP and SNPs. Basis of genetic mapping, Calculation of recombination

frequency by linkage analysis and Limitations of pedigree analysis. Genetic analysis of bacteria - gene transfer from one cell to another. Hybridization analysis and PCR, Restriction mapping, FISH. **Activity** - Prepare a model on successful story of Human Genome Project.

UNIT III Comparative and Functional Genomics LECTURE HOURS: 12

Comparative genomics- Identification and classification of organisms using molecular markers- 16S rRNA typing/ sequencing, SNPs and Pharmacogenomics; determining gene location in genome sequence, Human and other vertebrate Genome, Personal genomics, the minimal genome and the Barcode of Life. **Functional Genomics** - Transcriptome analysis for identification and functional annotation of gene, Contig assembly, chromosome walking and characterization of chromosomes, mining functional genes in genome, metagenomics. **Activity**- Retrieval/Analyzing of whole genome/partial sequences by using BOLD system.

UNIT IV: Proteomics LECTURE HOURS: 12

Introduction to Proteomics - Proteom at a glance, Functional protein families, Deducing protein from genome, Protein separations, protein analyses, Quantitative proteomics, Identification and analysis of proteins by 2D gel electrophoresis, Isoelectric focusing, Spot visualization and picking, Tryptic digestion of protein and peptide fingerprinting; **Comparative proteomics and Metabolomics** - Comparative proteomics - Isotope Coded Affinity Tag (ICAT) - principle, technique and applications. Metabolomics - Characterization of complete set of metabolites, principle and applications. **Activity** – Visualization of 3D structure of functional proteins by using Uniprot.

UNIT V: Bioanalytical and Bioinformatic Techniques LECTURE HOURS: 12

Protein structure visualization, Comparison and Classification - Protein structure visualization - Protein Data Bank, RasMol, Swiss-PDB Viewer, Molscript, WebMol, Ribbons, Grasp, Chime, Cn3D. **Microarrays** - DNA Microarrays - cDNA Microarrays, Differential gene expression and Identification of functionally

related genes. Oligonucleotide Micoarrays - Microarray data analysis. Protein Microarrays - Immobilized proteome, protein - protein interaction, protein - DNA/RNA interaction and Immunoassay. **Activity** - Prepare a working model for microarray with distinctive colour display.

Text Books:

T1 - Essential Bioinformatics, Cambridge University Press, Jin Xiong (2011)

T2 - Genomes, Edition:3 ,BIOS Scientific Publishers , T.A.Brown, 2007.

T3 - Proteomics, BIOS Scientific publishers, M.J.Dunn and S.R. Pennington (2002) Informatics in Proteomics

T4- Bioinformatics and Functional Genomics, Third Edition, Jonathan Pevsner. John Wiley & Sons, Inc. 2015.

Reference Books:

R1 - Bioanalytical Techniques, I.K. Inernational Publishing House Pvt.Ltd.,Sekhar Talluri (2012)

R2 - Introduction to Proteomics: Tools for the New Biology. Totowa, NJ: Humana Press. Liebler, D. C. (2002).

R3 - Protein Biochemistry and Proteomics. Hubert Rehm. Academic press, Elsevier, USA. 2006.

R4 - Genomics and Proteomics: Principles, Technologies, and Applications. Thangadurai, D., & Sangeetha, J. (Eds.). (1st ed.). Apple Academic Press, (2015). https://doi.org/10.1201/b18597

MP-II LAB IN GENETIC ENGINEERING AND PROTEIN CHEMISTRY

1. Isolation of genomic DNA from bacteria
2. Isolation of genomic DNA from animal tissue
3. Isolation of plasmid DNA from bacteria
4. Isolation of total RNA from bacteria
5. Bacteriophage isolation
6. Isolation of phage DNA
7. Ligation
8.Restriction Digestion
9. Competent cell preparation
10. Transformation
11. Denaturation of protein
12.2-D Gel Electrophoresis
13. Estimation of disulfide bonds in the isolated proteins

Text Books

T1.A Laboratory Manual of Analytical Methods of Protein Chemistry, Edition: II Elsevier P. Alexander, H. P. Lundgren(2014)

T2.Molecular Cloning ,Edition: I, Laboratory Manual, D.W. Russell & J. Sambrook.(2001)

T3. The Separation and Isolation of Proteins: a Laboratory Manual of Analytical Methods of Protein Chemistry, Edition:II, Revised Elsevier, P. Alexander, R. J. Block(2014)

EL-1A INTRODUCTION TO CLINICAL DATA MANAGEMENT

Course Title: **INTRODUCTION TO CLINICAL DATA MANAGEMENT (T)**	Course Code : **23 E**
Semester : **II**	Course Group : **M EL IA**
Teaching Scheme in Hrs (L:T:P) : **5:0:0**	Credits : **4 Credits**
Map Code : **C**	Total Contact Hours : **75**
CIA : **25 Marks**	SEE # : **75 Marks**
Programme : **M.Sc.,-BT**	# - **Semester End Exam**

No.	Course Outcome (COs): After completion of this course, the students will be able to	POs & PSOs	Cl. Ses.	CL
CO1	To define the principles of clinical data management and to illustrate the electronic transmission of data. Discuss the risk encountered in clinical studies.	PO1& PSO1	8	R, U
CO2	To outline the pharmacovigilance, expected and unexpected AE' and SAE's, time line for reporting SAE's. Describe the methods of monitoring drug safety. Prepare the case study on participants who are affected by ADR in clinical trials.	PO1& PSO1	7	U
CO3	To explain the study subjects, ethical committee, clinical trial management plan and investigational products. Demonstrate the clinical trial project plan by ICMR.	PO1& PSO1	15	R, U
CO4	To outline the essential components and organisational log of informed consent form and to practise on preparation of informed consent form.	PO1& PSO1	15	U, A
CO5	To discuss deviation from clinical study protocol and adverse drug effects in data and safety monitoring plans.	PO1& PSO1	15	U
CO6	To define the verification, maintenance and documentation of case report form and to prepare a model CRF for clinical studies.	PO1& PSO1	15	U, A

UNIT I - CLINICAL DATA MANAGEMENT: **Lecture Hours: 15**

Clinical Data Management - Definition, types, responsibilities, database design, data collection, data cleaning, data validation, **Principles of Data Management** - Definition,

types, data base design, collection, cleaning, validation, AEs and data archiving, **Query Resolution Process** - Introduction and query management, **Electronic Transmission of Data** - Introduction, definition, electronic source and documents, **The problems encountered in Counting Clinical Studies** - Introduction, risks in clinical trial and studies, **Activity** - List out the clinical trial studies takeaway hospitals and companies.

UNIT II: CLINICAL SAFETY DATA MANAGEMEN **Lecture Hours: 15**

Clinical Safety Data Management - Introduction, definition, terminology and standards for expedited reporting, **Pharmacovigilance** - Introduction, definition, role, monitoring and objectives, Adverse Event - Introduction, definition and types, **Adverse Drug Reaction** - Definition, classification and severity, Precautions, Report , and symptoms, **Expected and Unexpected Adverse Event and Serious Adverse Event** - Definition, types, classification, severity, Symptoms and its factors, **Time line for Reporting SAE's and the management** - Adverse Event Reporting, Adverse Drug Reaction Reporting and Serious Adverse Event Reporting, **SAE Reconciliation** - Introduction and explanation, **Safety reporting** - Introduction, Definition and safety tips, **Methods of Monitoring Drug Safety** - Introduction, Drug safety, safety signal – sources, process and language of drug safety, **Responding Drug Safety alerts** - Introduction, Drug Response and Safety Alerts, **Post marketing surveillance** - Introduction and Explanation, **Activity** - Case study on participants who are affected by ADR.

UNIT III: CLINICAL TRIAL MANAGEMENT **Lecture Hours: 15**

Clinical Trial Management - Introduction, project plan and explanation, **Investigator Site Perspective** - Study subjects, monitoring, communication with ethical committee, Protocol, investigational products, selection of study and records/reports, **Clinical Trial at the Site- Coordinating a Clinical Trial at the Site**. - Investigator's observation and CRF, **Activity** - Prepare a model project for ICMR.

UNIT IV: ESSENTIALS OF DOCUMENTATION **Lecture Hours: 15**

Required essential documents - Informed consent form - Process, signing, documentation, revision and reconsent, **Eligibility of Documents- Source documentation** - Determining eligibility and maintaining eligibility, **Adverse Events- Scope, Regulations, Organisation and External adverse event reports** - Adverse events comply with the regulations, **Organizational logs- Different logs** - Adverse event log, communication log, concominant log, enrollment log, protocol deviation log, specimen log, DOA log, **Activity** - Prepare a model on informed consent form and questionnaire.

UNIT V: DATA AND SAFETY MONITORING PLANS **Lecture Hours: 15**

Compliance with the DSMP and Monitoring Reports - Self-monitoring and monitoring reports, **Reporting requirements- Adverse events and Protocol deviations, Non-compliance and Monitoring reports** - Deviation from protocol, adverse drug effects, **Case Report Forms-** CRF completion, Verification, maintenance , storage, source Required essential documents - **Informed consent form** - Process, signing, documentation, revision and reconsent documentation, **regulation in patients** - Abbreviations for CRFs and Indian

regulation systems, **Activity** - Prepare a CRF model.

Text Books:

1. Practical Guide to Clinical Data Management, Third Edition, Susanne Prokscha, CRC Press, Taylor & Francis Group (2012).
2. Clinical Data Management Second Edition, Richard k. Rondel, Sheila A. Varley, Colin F. Webb, John Wiley & Sons Ltd, (2000).
3. ICH Topic E 2 A-Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, Edition:1, Westferry Circus, Canary Wharf, London, (2011).
4. Guidance for Industry Electronic Source Documentation in Clinical Investigations, Edition:1, U.S. Department of Health and Human Services, Food, (2013).

Reference Books:

1. Principles and Practice of Clinical Research, John I. Gallin, Frederick P. Ognibene, Laura Lee Johnson, 4th Edition, Academic Press, (2017).
2. A Clinical Trials Manual From The Duke Clinical Research Institute : lessons from a horse named Jim / Margaret B. Liu and Kate Davis. – 2nd ed, Wiley-Blackwell Publications, (2010).
3. Management Of Data In Clinical Trials, Eleanor Mcfadden, Second Edition, A John Wiley & Sons, Inc., Publication, (2007).

SEMESTER-III

M-X PLANT BIOTECHNOLOGY

No.	Course Outcome (Cos): After completion of this course, the students will be able to	POs &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	Describe the complete science of plant tissue culture.	PO1& PS01	6	R,U, A,C
CO2	Discuss about various novel products from plant cells.	PO1& PS01	6	R,U, A,C
CO3	Understand the genetic engineering principles in plant biology and also the importance.	PO1& PS01	12	R,U, A,C
CO4	Identify the plant vectors for genetic engineering studies.	PO1& PS01	12	R,U, A,C
CO5	Relate with the applications of Plant transgenics.	PO1& PS01	12	R,U, A,C
CO6	Classify the commercially important secondary metabolites.	PO1& PS01	12	R,U, A,C

UNIT I: INTRODUCTION TO TISSUE CULTURE LECTURE HOURS: 12

Suspension Culture - Isolation of cells, types of suspension culture, culture growth & cell viability, **Invitro Culture Laboratory Organization** - Laboratory structure, Requirements for media preparation & General technique for plant cell and tissue culture, **Tissue Culture Media Preparation** - Introduction, chemical composition of medium & medium preparation techniques, **Sterilization Techniques** - Introduction, range contaminants, methods of sterilization, equipment, sterilization of explants & precaution during sterilization, **Callus Culture** - Introduction, history, source tissue for callus induction & stages in callus growth and **Activity-** Formulate a optimal media for the growth of cereals

UNIT II: SOMATIC EMBRYOGENESIS LECTURE HOURS: 12

Somatic Embryogenesis - Introduction, principle of somatic embryogenesis, induction of somatic embryos & factors affecting somatic embryogenesis, **Micro Propagation** - Introduction, history, methodology, stages in sterile meristem culture, factors affecting meristem culture & application, **Somaclonal Variations** - History, existence of somaclonal variation, factors affecting somaclonal variation, frequency, selection, application & limitation, **Anther Culture** - Source of anther, pathway of *in vitro* androgenesis, factors affecting anther culture, uses & limitation, **Embryo Culture** - Methodology, history, *in vivo/in vitro* embryogeny & embryo nurse endosperm technique, **Somatic hybridization** - Isolation of protoplast, methods, major fusogens, other fusogens & identification, selection of other protoplast, **Synthetic Seeds** - Concept of synthetic seed, production, principle& advantage, **Germ plasm Conservation** - Definition, *insitu, exsitu*, germplasm conservation from seeds, *in vitro* methods &application, **Cryopreservation** - Definition, mechanism, precaution/limitation, & technique, **Hardening and Acclimatization of Tissue Cultured Plants** - Hardening chamber & green house or acclimatization room and **Activity-** Identification of an endangered plant and to optimize conditions for the micropropagation of the same

UNIT III: Ti-PLASMID **LECTURE HOURS: 12**

Agrobacterium infection & Properties of Crown gall - Crown gall disease & Ti plasmid, **Organization of T-DNA ,Transfer of T-DNA& Integration of T-DNA into plant genomes** - Organization of Ti plasmid, transfer ,integration & hairy root disease A.rhizogenes, **Vectors Derived from Ti Disarming, Co integrate vectors &Binary Vectors** - Production of disarmed Ti plasmid, cointegrate, binary& plant transformation technique, **Direct Gene Transfer- Electroporation, Particle gun method** - Technique, advantage,limitation & plant material, transgene integration, factors affecting particle gun, advantage & limitation, **Lipofection and Microinjection** - Advantages of liposome fusion, limitation of liposome fusion & definition of microinjection, **Macroinjection & Silicon carbide fiber mediated transformation** - Macroinjection technique & silicon carbide fibers **Chemical Methods- PEG mediated genetransfer, Calcium phosphate co precipitation** - PEG gene transfer & calcium chloride solution, **Poly cation DMSO technique, DEAE dextran procedure** - DMSO technique, DEAE dextran. Advantage &Disadvantage and **Activity-** Locate a desired gene and explore it's cloning strategies.

UNIT IV: TRANSGENIC PLANTS **LECTURE HOURS: 12**

Insect Resistance - Bt toxin, genes, mode of action of cry genes,biopesticide,advantage,proteinase, cowpeatrypsin & lectins, **Virus Resistance** - Virus coat protein, limitation, movement, transmission & satellite RNAs, **Resistance to Abiotic Stresses** - Herbicide resistance, glyphosphate, phosphinothricin, sulfonyl urea, tolerance to water & resistant against ice nucleating bacteria, **Improvement of crop yield and Quality** - Green revolution, genetic engineering for extended shelf life of fruits &biochemical changes during tomato ripening, **Transgenic plants with Improved Nutrition** - Amino acid for seed storage protein, genetic engineering for improving palatability of foods, golden rice & genetic engineering to increase vitamins and minerals.**Transgenic Plants as Bioreactors- Metabolic engineering of Carbohydrates & Lipids** - Starch, cyclodextrins, fructans, fatty acids & bioplastics, **Genetically engineered plants as protein factories** - Protein production in plants, oleosin partition technology & production of industrial enzymes in plants, **Plantibodies** - Production and use & production of secretory IgA & production of other antibodies, **Molecular marker aided plant breeding- Molecular Markers** - Basic principle, DNA hybridization, RFLP, RAPD, PCR, AFLP, STS & microsatellites, **Molecular Marker Assisted Selection** - Molecular breeding, linkage analysis & quantitative trait loci and **Activity-** Plantibodies - Current Research, Success stories and Challenges.

UNIT V: PRODUCTION OF SECONDARY METABOLITES

LECTURE HOURS: 12

Strategies used to Optimize Product Yield- Culture Condition - - Introduction, natural plant products and cell culture production –shikonin, **Selection of High Yielding Lines** - - Heterogeneous culture, screening for high yielding lines and shikonin producing cell lines, **Elicitation, Immobilization of cells** - Elicitor, organic or inorganic molecules, dimeric alkaloids, biomass production by suspension culture & cell density in bioreactor, **Hairy root culture** - Tropane alkaloid, hairy root disease and betacyanin, **Biotransformation** - Chemical conversion, arbutin &dimeric indole alkaloids, **Permeabilization of cells,Removal of secreted products** - - DMSO, low pH, sonication and continuous ultra sound Enzymatic or non enzymatic degradation, indole alkaloids, activated charcoal and dimethyl siloxane polymer, **Pharmaceutically, Agriculturally important Chemicals Food Colouring Agents** - Alkaloids, morphine, berberine, tropane alkaloids, antitumour compounds and virus

inhibitors Saffron, shikonin, anthocyanins, safflower yellow and chicle and **Activity-** To develop a protocol for isolation of commerciallly important secondary metabolite.

Text Books

T1-Plant Biotechnology, Edition:I, MJP Publishers,Chennai, Vikrant and Mahipal Singh and Shekhawat (2011).
T2-Plant Tissue Culture, Edition:V, Elsiever Publication, Bhojwani S.S and Razdan M.K(2004).

Reference books

R1-A Textbook of Biotechnology, Edition:II, S.Chand & Company Limited, New Delhi, R.C Dubey(2009).
R2-Biotechnology, Edition:I, Books & Allied Private Limited, Kolkata, Dr. U. Satyanarayana(2010).
R3- Introduction to Plant Biotechnology, Edition:II, Oxford & IBH Publishing Co.Pvt. Ltd. Oxford & IBH Publishing Co.Pvt. Ltd.(2008).

M-XI ANIMAL BIOTECHNOLOGY

No	Course Outcome (Cos): After completion of this course, the students will be able to	POs &PSOs	Cl.Ses	CL
CO1	Explain the role of laboratory equipments in animal tissue culture	PO1 & PSO1	12	U
CO2	Discuss the objectives and elements of aseptic techniques	PO1 & PSO1	12	U
CO3	Describe the physical, chemical and metabolic functions of different constituents of cell culture medium	PO1 & PSO1	12	U
CO4	Explain the mechanism of disaggregation of animal tissue, primary culture and organ culture	PO1 & PSO1	6	U
CO5	Describe the principle and techniques of cell separation, cell synchronization, cryopreservation, apoptosis and cytotoxicity assays	PO1 & PSO1	6	U
CO6	Discuss the process of transgenesis and their applications, production of transgenic animals and chimeric production	PO1 & PSO1	12	U

UNIT I: LABORATORY EQUIPMENTS LECTURE HOURS: 12

Advantages of Animal Tissue Culture - Control of the Environment, Characterization and Homogeneity of sample, Economy, Scale and Mechanization, *In vitro* Modeling of *In vivo* conditions, **Aseptic area** - Laminar - Flow Hood, Pipette Cylinders, Aspiration Pump, Service Carts, Inverted Microscope, Centrifuge, Sterile Liquid Handling - Pipetting and Dispensing, Cell counter, CCD Camera Monitor and Dissecting Microscope, **Incubation** - Incubator, Humid CO2 Incubator, Temperature Recorder, Roller racks and Magnetic stirrer, **Storage, Specialized Equipments** - Refrigerators and Freezers, Cryostorage Containers and Controlled - Rate Freezer, Specialized Equipments and **Activity** - Prepare a model for animal cell culture laboratory with standard norms.

UNIT II: ASEPTIC TECHNIQUES LECTURE HOURS: 12

Objectives and Elements of Aseptic Techniques - Maintaining sterility, Quit Area, Work Surface, Personal Hygiene, Reagents and Media, Cultures, **Sterile Handling** - Swabbing, Capping, Flaming, Handling Bottles And Flasks, Pipetting and Pouring, **Ionizing Radiation** - Ingestion, Disposal of Radioactive Wastes, Irradiation from labeled reagents, and

Irradiation from high energy sources, **Biohazards, Culture Vessels and Substrates** - Levels of Biological contaminant, Microbiological safety cabinets, Human Biopsy Material, Genetic Manipulation, Disposal of Biohazardous waste, Fumigation, Attachment and Growth, Substrate Materials, Cell Yield, Suspension Culture, Venting, Sampling and Analysis, Uneven Growth and Cost and **Activity-** Prepare a protocol for standard operating procedures of animal cell culture laboratory

UNIT III: DEFINED MEDIA AND SUPPLEMENTS LECTURE HOURS: 12

Culture Media; Balanced Salt Solutions and Simple Growth Medium - Composition, Balanced Salt Solution - inorganic salts, Aminoacids and Vitamins, Hank's Balanced Salt Solution, Carbondioxide tension, Suspension Culture, Growth factors, Hormones, Nutrients and Metabolites. **Physical, Chemical and Metabolic functions of different constituents of culture medium** - pH, Carbondioxide and bicarbonate, buffering, oxygen, osmolality, temperature, viscosity, surface tension and foaming. Constituents - Aminoacids, Vitamins, Glucose, Antibiotics, Hormones and growth factors **Role of Carbon oxide, Serum, Growth factors, Glutamine in Cell culture, Serum Free Media** - Characteristics, formation of bicarbonate, Relationship between bicarbonate, carbon dioxide and HEPES, Serum - role, source and its functions, calf serum and fetal bovine serum, , Growth factors - role of antibiotics, hormones, lipids and minerals in culture medium, Disadvantages of serum, Advantages of Serum -Free Media -Selective Media, Disadvantages of Serum -Free Media - Multiplicity of Media, Selectivity, Reagent Purity, Cell Proliferation and Availability. Protein Free Defined Media and their Applications and **Activity** - Prepare a chart on role of BSS in animal cell culture medium

UNIT IV: TYPES OF CELL CULTURE LECTURE HOURS: 12

Primary and Established Culture - Disaggregation of Tissue and Primary Culture, Isolation of Tissue, Enzymatic Disaggregation (Trypsin and Collagenase), and Mechanical Disaggregation. **Organ Culture, Tissue Culture** - Solid Medium , Liquid Medium, Culture of Embryonic organs, Organ Culture on Plasma clots and Organ Cultures on Agar. **Three Dimensional Culture and Tissue engineering, Feeder layers** - Regenerate, repair and replace, Cell based therapies, Scaffolds, Muscular dystrophy and Artificial vessels. **Disaggregation of Tissue and Primary cell culture** - Primary Culture- Primary explant, Disaggregation of Tissue- Enzymatic Disaggregation and Mechanical Disggregation. **Cell Separation** - Cell density, Cell size and Sedimentation velocity, Antibody based techniques- Immune panning, Magnetic sorting and Fluorescence -Activated Cell Sorting. **Cell Synchronization** - Introduction, Estimating Cell Cycle Phase durations, Synchronizing cells, Problems in interpreting Cell Synchrony experiments. **Cryopreservation** - Acquisition of cell lines for Cryopreservation, Principles of Cryopreservation - Cell concentration, Freezing medium and Cooling rate, Cryofreezers, Storage system, Design and Control of Freezer stocks and Cell banks. **Apoptosis and its Determination** - Introduction, Cellular Measurement of Apoptosis and Biochemical measurement of Apoptosis, **Cytotoxicity Assays** - Viability, Toxicity and Survival, *In vitro* limitations, Assays based on Cell Proliferation, Metabolic Cytotoxicity assays, Microtitration assays, MTT assays and Applications of Cytotoxicity assays and **Activity -** Prepare a working model of scaffolds

UNIT V: TRANSGENIC ANIMALS LECTURE HOURS: 12

Concept of Transgene and Transgenesis - Heterologous DNA, Transgenics, *In vitro*, Germline, Genetic Material, Homologous, Fertilized or unfertilized eggs, Pronuclear microinjection **Transgenic animals - Production and Applications** - Method of Production - Microinjection, Use of Retroviral vectors and Embryonic stem cell transfer. Applications of

Transgenesis - Disease Model, Improving livestock and Molecular Pharming. **Transgenic Animals as Models for Human Diseases, Transgenic in Industry, Chimeric Production** - Transgenic animals as disease models, Generating a mouse model, *In vivo* and *In vitro* model, Transgenic Animal Models -Transgenic mice and Cancer. Recombinant vaccines and therapeutics and Production of valuable proteins. Chimeric Production - Technique in mice, knockout gene transfer procedure and generation of chimeras and
Activity - Success stories of transgenic animals

Text Books:

T1. Culture of Animal Cells, Edition: 5, John Wiley Publication, Ian Freshney R (2005)
T2. Animal Cell Culture Methods, Edition: 1, Academic Press,| David Barnes and Jennie P. Mather
T3. Animal Biotechnology | Edition: 3, Agrobios (India), M. M. Ranga (2013)

M-XII PHARMACEUTICAL BIOTECHNOLOGY

No.	Course Outcome (Cos): After completion of this course, the students will be able to gain knowledge on pharmacy	POs &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	Understand the Knowledge on history, classification, source, nature of drugs	PO1& PS01	6	R,U, A,C
CO2	Remember dose, routes of drug supply and ADME of drug	PO1& PS01	6	R,U, A,C
CO3	Describe mechanism of receptor and its types.	PO1& PS01	12	R,U, A,C
CO4	Discuss the phases of metabolism in drug.	PO1& PS01	12	R,U, A,C
CO5	Remember the pathological aspects of disease	PO1& PS01	12	R,U, A,C
CO6	Understand the drug discovery process	PO1& PS01	12	R,U, A,C

UNIT I: DRUGS **LECTURE HOURS: 12**

History - Definition, Terms and History of Drugs, **Sources and nature** - Sources- Mineral, Animal, plant, Synthetic, Microorganisms and Genetic engineering **Classification and Nomenclature** - Pharmacological classification of drugs- Autonomous Nervous System, CNS, Gastrointestinal System, cardiovascular system Drugs acting on kidney, blood and blood forming organs, endocrine system, vitamins, Respiratory system, Autocoids, Chemotherapeutic agents and drugs used in treating poisoning, **Dosage of drug** - Coloring agent, Sweetening agent , Flavoring agent, solid dosage form and dosage form for external administration, **Routes of administration** - Local application, oral administration, Parental routes of administration- Inhalation, Injections, Transcutaneous and Trans mucosal route, **ADME of drug** - Absorption, Bioavailability, Distribution, Metabolism and excretion of drug and **Activity-** Prepare a protocol on various drug preparation from plant sources

UNIT II: DRUG PROTEIN INTERACTION **LECTURE HOURS: 12**

Introduction - Drug receptor interaction, Receptor theory, Regulation, Affinity and intrinsic activity, Potency and efficacy, non receptor mechanism and combined effects of drugs, **Receptors – Types and biological role** - Definition, Types-Channel linked receptor, Enzyme linked receptor, G-protein coupled receptor and Intracellular receptor and importance, **Protein Hormone receptors** - Introduction, Peptide hormone receptor- G protein coupled receptor- cAMP & Phosphatidylinositol signal pathway, **Steroid hormone receptors** - Introduction, Glucocorticoid, estrogens, androgens hormone and Sensory receptor, **Developmental receptors** - Introduction and Epidermal growth factor receptor, **Lipid receptors.** - Introduction, lipid receptor and its structure and **Activity -** Prepare the list of vegetables/fruits that interfere the absorption of drugs.

UNIT III: DRUG METABOLISM **LECTURE HOURS: 12**

Drug metabolizing enzymes - Cytochrome P450 monooxygenase system, Alcohol dehydrogenase and aldehyde dehydrogenase | Monoamine oxidase and cytochrome P450 reductase, Esterases and amidases Epoxide hydrolase, **Phase I reaction** - Introduction, Oxidation, reduction and hydrolysis, **Phase II reaction** - Methylation, Sulphation, Acetylation and Glucuronidation, **Enzyme induction** - Definition, Stimulatory effect and

Inducer, **Drug toxicity** - Definition, classification and severity, Precautions, Report , safety tips and Symptoms, **Factors affecting toxicity** - Factors and its Explanation and **Activity-** Indentify the list of synthetic drugs which can cause side effects.

UNIT IV: CANDIDATE DRUG ASSESSMENT LECTURE HOURS: 12

Clinical trials - Definition and phases of clinical trial, **Pharmacogenetics** - Principles and applications of pharmacogenomics, **Impact of genetic polymorphisms on drug efficacy** - Introduction and different enzyme profile on drug efficacy, **Pathological aspects and drug therapy of epilepsy** - Introduction, Epidemiology and Treatment, **Pathological aspects and drug therapy of Alzheimer's disease** - Introduction, Risk factor, Symptoms, diagnosis and treatment, **Pathological aspects and drug therapy of Parkinson** - Definition, symptoms, clinical pathology and treatment, **Drug addiction and drug abuse** - Drug abuse, Drug addiction, Classification of Addictive Drugs and treatment and **Activity-** Prepare the case study for a selective disease.

UNIT V: DRUG DEVELOPMENT LECTURE HOURS: 12

Target identification - Area influencing drug discovery, Parameters in drug discovery and Process-Target identification, **Target validation** - Introduction, Chemogenomics and TGD, **Lead discovery and optimization** - Virtual screening, Chemoinformatics, Pharmacophore mapping, QSAR, High throughput docking, NMR screening and chemical genetics, **Animal models** - Introduction and Laboratory animals, **Computer aided drug designing (CADD)** - Drug design approaches, Ligand based approach and Target based approach, **Structure based drug design** - Introduction, Drug design approaches and structure based design, **QSAR, HTP screening** - Definition, QSAR and High throughput screening, **Molecular docking** - Definition, Docking Process and scoring functions and **Activity-** To prepare the imaginary drug for any one particular disease.

Text Books

T1-Introduction to Pharmacology, Edition: 1, Vallabh Prakashan, P. C. Dandiya and S. K. Kulkarni (1997)

T2-Bioinformatics Methods and Applications, Edition: 1, Prentice Hall of India Pvt Ltd, New Delhi, S. C Rastogi *et al* (2004)

T3-Biopharmaceuticals: Biochemistry and Biotechnology, Edition: 2, John Wiley and Sons, Chichester, Gary Walsh (2003).

Reference books

R1-Pharmacology and Pharmacotherapeutics, Edition: 16, Mumbai Popular Prakashan, R. S. Satoskar, S. D. Bhandarkar and S. S. (1999).

R2-Essentials of Pharmacotherapeutics, Edition: 1, S. Chand and Co., Ltd., New Delhi, Barar, F. S. K (2004).

R3-Molecular Modeling: Principles and Applications, Edition: 2, Pearson Education EMA, Andrew R. Leach (2001).

MP- III LAB IN PLANT AND ANIMAL BIOTECHNOLOGY

PLANT BIOTECHNOLOGY

1. *In vitro* germination of Seeds
2. Callus induction and Differentiation
3. Somatic embryogenesis
4. Isolation and Fusion of Protoplast
5. Meristem culture and Micropropagation
6. Agrobacterium mediated Gene Transfer
7. Artificial Seed Production

ANIMAL BIOTECHNOLOGY

1. Demonstration of Scanning Electron Microscope (SEM) & inverted confocal microscope
2. Preparation of Tissue culture medium and Balanced Salt Solution
3. Retrieval of organs from Chick Embryo
4. Trypsinization of tissues from embryo organs and maintenance of primary culture
5. Cell Counting and Cell Viability
6. MTT assay
7. Separation of Poly Morpho Nuclear Leucocytes from Human blood
8. DPPH radicals scavenging assay

Reference Books

1. Animal Cell Culture, A Practical Approach, Edition: IV, John Wiley Publication, Freshney. R. I (2012)
2. In vitro Culture of Higher Plants, Edition: 1, Pierik R. L. M (2009)
3. Plant Cell Culture, A Practical Approach, and Edition: II, Dixon R. A (2010)

EL-II PROJECT MANAGEMENT, PRINCIPLES OF PHARMACOECONOMICS & PHARMACOGENOMICS

No.	Course Outcome (Cos): After completion of this course, the students will be able to	POs &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	Discuss on the basic concepts of research.	PO1& PS01	12	R
CO2	Describe the sponsor perspectives and Investigators perspective.	PO1& PS01	6	R
CO3	Discuss on the ethical committee role of function and producers.	PO1& PS01	6	U
CO4	Outline the procedures used in record keeping and data handling	PO1& PS01	12	R
CO5	Recall the history of Toxicology and development of scope.	PO1& PS01	12	R
CO6	Illustrate the flow chart preparing and drug development.	PO1& PS01	12	A

UNIT I: RESEARCH **LECTURE HOURS: 12**

Steps in research - Selection, survey, methodology, design and report, **Literature collection** - Review of literature, review process & bibliography and research reading, Discriminative reading, consulting source material, working bibliography, index cards and reference cards, **Literature citation** - Different system of citing references, Name- year system- citation in the text and name -year system -list of references. Citation sequence system, Alphabet number system and journal abbreviations, **Research report** - Introduction, component of research report –Title, Authors & addresses, Abstract, Summary, Synopsis and Key words.

Experimental design - Observation, hypothesis and null hypothesis and basic principles of experimental design, **Basic and Applied research** - Research, research in biology, basic research and applied research

UNIT II: SPONSOR PERSPECTIVES **LECTURE HOURS: 12**

Investigator perspectives - Investigator and institution selection, allocation of duties and responsibilities, study management, **Sponsor perspectives** - Data handling and record keeping, confirmation of review by the ethics committee, information on investigational products, supply, storage and handling of products, **Ethical committee** - ADR reporting, study reports, monitoring, audit, multicentre studies, multicentre studies, premature termination and role of foreign sponsor, **Sponsor responsibilities** - Monitor- qualification and responsibilities, **Role of Investigator** - Investigator- qualification, medical care, monitoring auditing of records, communication with ethics committee, compliance with the protocol, investigational products, selection and recruitment of study subjects and records

UNIT III: RECORD KEEPING AND DATA HANDLING LECTURE HOURS: 12

Record keeping and data handling - Record keeping and data handling, documentation and corrections, **Electronic data handling** - Electronic data processing and validation, language, responsibility of investigator, sponsor and monitor, **Quality assurance** - Introduction and explanation, **Statistics** - Role of biostatistician, study design and analysis. Methods of data collection, presentation. Measurement of central tendency, variation, mean, median, mode, ANOVA- types, statistical methods- t test, chi test. Statistical tools- Graph Pad Prism, MS Excel, introduction to SPPS software.

UNIT IV: TOXICOLOGY LECTURE HOURS: 12

Scope of Toxicology - Definition, Development and Scope of Toxicology, **Classification of toxic agents & Factors influencing toxicity** - Target organ toxicity, based on intended use, source, physical state, chemical nature and biochemical mechanism Factors related to substance, subjects and to exposure, **Prevention and treatment of poisoning** - Goals, Treatment of acute poisoning and dose-effect relationship in toxicology, **Toxicity studies in animals** - Acute toxicity test, Sub acute toxicity test and Chronic toxicity test, **Toxicity studies in man** - Drug intolerance, Haemopoietic toxicity, Hepatotoxicity, Neprotoxicity. Ototoxicity, Ocular toxicity, Behavioral toxicity, Unmasking and exacerbation of disease, **Toxicity studies in man** - Iatrogenic disease, Electrolyte disturbances, endocrine disturbances, Skin toxicity, carcinogenesis and teratogenicity, drug dependence, drug interaction and ADR drug withdrawal.

UNIT V: REGULATIONS LECTURE HOURS: 12

Regulatory Affairs - Introduction, Professional and Importance, **Regulatory Audit** - Introduction, process, roles and responsibilities, and audit activities, **Regulatory requirements for biotechnological products** - Introduction, responses , ADR, Risk and risk management, **Regulatory requirements for the preparation, packaging, labeling and storage of Clinical trial drugs** - Introduction, personal, facility & equipment, container, glassware's, laboratory controls, packaging, labeling and distribution, **Health economics** - Definition, Flowchart and contribution, **Pharmacoeconomics** - Introduction, research, Methodology, Drug development, Guidelines, Challenges.

Text Books:

T1-Good clinical practices for clinical research in india, Edition:1, Consortium, Clinical Research Pvt Ltd, -(2008).
T2-Pharmacology and Pharmacotherapeutics, Edition:16, Popular Prakashan, Mumbai, R. S. Satoskar *et al* (1999).

Reference Books:

R1-Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers, Edition:1, Dr. Roland Rotter (2008).
R2-Guidance foe Industry, U S Department of health and human services, Edition:1,(2008).
R3-Introduction to Pharmacoeconomics, Edition:1, J. Lyle Bootman and Raymond J. Townsend and William F McGhan (2002).

EL-III FORENSIC SCIENCE

No.	Course Outcome (Cos): After completion of this course, the students will be able to	Pos &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	To examine the physical evidences associated with suspect in a crime	PO1& PS01	12	R, U, A
CO2	To familiarize various impressions collected from the crime scene	PO1& PS01	12	R, U, A
CO3	To discuss the importance of Blood & soil collected from the crime scene	PO1& PS01	12	R, U, A
CO4	To discuss the importance of casts & impression as a evidence	PO1& PS01	6	R, U, A
CO5	To analyze the mechanism, manner and time of death	PO1& PS01	6	R, U, A
CO6	To understand the importance of hair, fingerprints, nail, bone, and tire marks as a evidence	PO1& PS01	12	R, U

UNIT I: OBSERVATION SKILLS, CRIME SCENE INVESTIGATION, EVIDENCE COLLECTION AND PRESERVATION LECTURE HOURS: 12

Observation in forensic science - Introduction, definition of observation, observation of witnesses, observation in forensics, case studies, **Crime scene investigation, evidence collection and preservation**- Introduction, principle of exchange, types of evidence, crime scene investigation team, the seven S's crime scene investigation, analyze the evidence, crime scene reconstruction, staged crime scenes, preservation and case studies.

UNIT II: HAIR, FINGER PRINTS AND GLASS AS EVIDENCE

ECTURE HOURS: 12

The study of hair - Introduction, history of hair analysis, functions of hair, structure of hair, case studies, **Finger prints** - Introduction, historical development, history of biological evidence in forensics, function and structure of DNA, DNA identification, source of DNA, collection and preservation of DNA evidence, DNA and probes, analysis of DNA finger prints, case studies, **Glass evidence** -Introduction, History of glass, Types of glass, Properties of glass, Case studies

UNIT III: BLOOD, SOIL AND BONE AS EVIDENCE LECTURE HOURS: 12

Blood and blood spatters - Introduction, blood history, composition of blood, blood spatter, crime scene investigation of blood, Case studies, **Soil examination** - Introduction, history of forensic soil examination, soil composition, sand, soil collection and examination, Case studies, **Bone** - Introduction, characteristic of bone, skeletal trauma analysis, case studies.

UNIT IV: CASTS AND IMPRESSION AND BALLISTICS AS EVIDENCE

LECTURE HOURS: 12

Casts and impression - Introduction, shoe impressions, tire treads and impressions, dental impressions, case studies, **Ballistics:** - Introduction, history of gunpowder and firearms, long guns and handguns, firearms and rifling, bullets, cartridges and calibers, gunshot residues, bullet wounds, case studies.

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UNIT V: DRUG IDENTIFICATION, HANDWRITING ANALYSIS AND DEATH

LECTURE HOURS: 12

Drug identification and toxicology - Introduction, history, case studies, **Handwriting analysis, forgery and counterfeiting** - Introduction, history, handwriting examination, counterfeiting, case studies, **Death: -** Introduction, manner of death, cause and mechanism of death, time of death, case studies

Text Books:

T1. Forensic science: Fundamentals and investigations, Edition: I, South-Western Cengage Learning, Anthony J. Bertino and Patricia Nolan Bertino (2009).

Reference Books

T1. Forensic science: An introduction to scientific and investigation techniques, Edition: IV, CRC Press, Jon J. Nordby and Stuart H. James AND Suzanne Bell (2014)

T2. Forensic science: Principle and application, Edition: 2| Ancient Publishing House, Nishant Singh (2011).

SEMESTER- IV

M-XIII- BIODIVERSITY, BIOETHICS & IPR

No.	Course Outcome (Cos): After completion of this course, the students will be able to	Pos &PSOs	Cl.Ses	BLOOM'S TAXONOMY LEVEL
CO1	To understand the levels, values and loss of biodiversity at national and international level	PO1& PS01	12	R, U, A
CO2	To learn about Framework for Ethical decision making Ethical aspects	PO1& PS01	12	R, U, A
CO3	To study about Ethical implications of cloning	PO1& PS01	12	R, U, A
CO4	To understand Biosafety issues in biotechnology, risk assessment and risk management	PO1& PS01	12	R, U, A
CO5	To learn Guidelines and Regulations of Operation Biosafety	PO1& PS01	6	R, U, A
CO6	To understand the IPR & its types	PO1& PS01	6	R, U, A

UNIT I: INTRODUCTION TO BIODIVERSITY LECTURE HOURS: 12

Levels of Biodiversity - Genetic, Population, Species and Ecosystem diversity **Values of Biodiversity** - Direct and Indirect Values **Loss of Biodiversity** - Habitat loss, Climate Change, Industrilization, Overexploitation and unsustainable use and Deforestation **Species Concept Classification and Systematic concept** - Biological Nomenclature and classification **Biodiversity Conservation Insitu and Exsitu Conservation** - Mode and Principles**agnitute and Distribution** - Range of magnitude and levels of distribution **Wildlife biology** - Geographical explanation and components **Conservation Strategies Measures of biodiversity** - Biodiversity measurements **Biodiversity in India and Global level** - Different biodiversity spheres in India and Global level range of biodiversity **Biodiversity hotspots** - List of hotspots of biodiversity

UNIT II: ETHICS/BIOETHICS LECTURE HOURS: 12

Framework for Ethical decision making - Approaches to ethical thought-Hippocratic oath, Utilitarian approach, deontological approach and ethical excercise warmup, **Biotechnology and Ethics** - Biotechnology in Agriculture and Environment: benefits and risks, **Ethical aspects** - Ethical aspects of genetic testing relating to use of genetic information and biowarfare

UNIT III: ETHICAL IMPLICATIONS OF CLONING LECTURE HOURS: 12

Reproductive cloning and therapeutic cloning - ethical implications of Reproductive cloning and therapeutic cloning **Ethical, legal and socio-economic aspects Gene therapy, germ line, Somatic, Embryonic and Adult stem cell research** - Ethical, legal and socio-economic aspects of gene therapy, germ line, Somatic, Embryonic and Adult stem cell research **GM crops and GMO's Transgenic plants and genetically modified organism** - Bt Cotton, FLAVR SAVR, SUPER BUGS **Biotechnology and biopiracy Introduction** - The commercial development of naturally occurring biological materials **ELSI of human genome project Ethical, Legal, social and issues of human genome**

project - Privacy and fairness, The integration of new genetic technologies, Ethical issues and education of healthcare professionals

UNIT IV: BIOSAFETY **LECTURE HOURS: 12**

Biosafety issues in biotechnology, risk assessment and risk management - Issues of concern, prevention mechanism- risk assessment analysis and comparative analysis **Biosafety levels** - Levels of biosafety 1, 2, 3 and 4 **Biosafety guidelines and regulations** - National and International guidelines and regulations **Guidelines and Regulations of Operation Biosafety** - IBSC, RCGM, GEAC, MEC and ICAR **Biosafety Containments** - Types- Fume hood, Laminar flowhood, Class I, II and III

UNIT V: IPR **LECTURE HOURS: 12**

Introduction to IPR and its types - Patents, Copyrights, Trademark, Design rights and Geographical indications **Importance of IPR** - Patentable and Non patentable, Patenting life **Legal Protection** - Biotechnological inventions **WIPO** - World Intellectual Property Rights Organization and properties for patenting details

Text Books:

T1.A Textbook of Biotechnology, Edition: 4th, S.Chand and Company Ltd, R.C.Dubey(2012)

T2. Biosafety in Industrial Biotechnology, Edition: 1st, Blackie Academic and Professional , J.Melling and P.Hambleton and T.T.Salsbury(1994)

Reference Books:

R1. Glimpses of Biodiversity, Edition:II, Academic Press , B.Bltosetti(2002)

R2. Introduction to Biotechnology, Edition:2nd,Pearson, Micheal APalladino and William JTheiman(2009)

MP-IV LAB IN PHARMACEUTICAL BIOTECHNOLOGY AND BIOINFORMATICS

1. Handling of Mice, Rat, Rabbit, Guinea Pig and Frog
2. Study on different routes of Administration of drugs
3. Study of General Anesthetics
4. Analgesic effect of morphine in Mice using hot Plate Method
5. Analgesic effect of Pentazocine by hot Water Tail Immesion Method
6. Study the effect of drugs on rabbit eye
7. Study of locomotary activity in mice using Actophotometer
8. Study of Muscle Relaxant Property in mice using Rota Rod
9. Study of Muscle Relaxant Property in mice using Rota Rod
10. Sequnce similarity search using FASTA & BLAST
11. Usage of searching tools such as PubMed, Bookself and Structure prediction

Reference

T1-Introduction to Pharmacology, Edition:1, Vallabh Prakashan, P. C. Dandiya and S. K. Kulkarni(1997)