SEMESTER WISE TITLES OF THE PAPERS IN U.G. (HONOURS), U.G. (HONOURS WITH RESEARCH) IN BIOTECHNOLOGY

YEAR	SEM	COURSE	PAPERTITLE	THEORY/	CREDIT	TOTAL
		CODE		PRACTICAL		
4 TH YEAR		RB100701T	BIOCHEMISTRY & ENZYMOLOGY	THEORY	4	
		RB100702T	MICROBIAL PHYSIOLOGY &	THEORY	4	
	VII		GENETICS			
			Choose both for U.G.(Honours) and one for			
			U.G. (Honours with Research)-			
		RB100703T	I. CELL BIOLOGY	THEORY	4	
		RB100704T	II. BIOSTATISTICS &	THEORY	4	20/16
			COMPUTER APPLICATION			
		RB100705P	PRACTICAL	PRACTICAL	4	
		RB100801T	BIOANALYTICAL TECHNIQUES	THEORY	4	
		RB100802T	MOLECULAR BIOLOGY	THEORY	4	
			Choose both for U.G. (Honours) and one for	THEORY		
	VIII		U.G. (Honours with Research)-			
		RB100803T	I. IMMUNOLOGY	THEORY	4	20/24
		RB100804T	II. NANOTECHNOLOGY	THEORY	4	
		RB100805P	PRACTICAL	PRACTICAL	4	
		RB100806R	Research Project (Submission and E	8		

SEMESTER WISE TITLES OF THE PAPERS IN POSTGRADUATE COURSE IN BIOTECHNOLOGY

		RB100901T	ANIMAL BIOTECHNOLOGY	THEORY	4	
STHYEAR	IX	RB100902T	PLANT BIOTECHNOLOGY	THEORY	4	16
		RB100903T RB100904T	Choose any one— I. FOOD BIOTECHNOLOGY OR III. PHARMACEUTICAL BIOTECHNOLOGY	THEORY	4	
	X	RB100905P	PRACTICAL	PRACTICAL	4	
		RB101001T	RECOMBINANT DNA TECHNOLOGY	THEORY	4	
		RB101002T	MEDICAL BIOTECHNOLOGY	THEORY	4	24
		RB101003T RB101004T RB101005P	Choose any one— I. BIOENTREPRENEURSHIP OR II. CLINICAL BIOTECHNOLOGY	THEORY	4	
		RB1010031	PRACTICAL PRACTICAL Research Project (Submission and Evaluation)		8	

RB10701-BIOCHEMISTRY & ENZYMOLOGY:

Unit-I: Introduction and protein structure:-

Chemical basis of life; Composition of living matter; Water – properties, pH, ionization and hydrophobicity; Emergent properties of biomolecules in water; structure of proteins: protein folding and mis-folding, primary and higher order structures; structure-function relationships in model proteins: ribonuclease A, myoglobin, hemoglobin, chymotrypsin.

Unit-II: Carbohydrates and lipids

Carbohydrates; mono, di, and polysaccharides; suitability in the context of their different functions- cellular structure, energy storage, glycosylation of other biomolecules - glycoproteins and glycolipids; Lipids structure and properties of important members of storage and membrane lipids; lipoproteins.

Unit-III: Membranes and Nucleic acids

Biomembrane organization - sidedness and function; Membrane bound proteins - structure, properties and function; membrane transport, nucleic acids- structure, diversity and function. Unit – IV: Bioenergetics

Bioenergetics-basic principles; Equilibria and concept of free energy; Coupled processes;

Glycolytic pathway; Kreb's cycle; Oxidative phosphorylation; Photosynthesis; Elucidation of metabolic pathways; Logic and integration of central metabolism; entry/ exit of various biomolecules from central pathways; Principles of metabolic regulation.

Unit-IV: Secondary Metabolites

Terpenes (sesquiterpenes, carotenoids), alkaloids, flavonoids, targeting mevalonic acid pathway/ MEP pathway in bacteria, phenolic compounds, shikimic acid pathway, importance of secondary metabolites.

Unit-V: Enzymology

Enzymes, Enzyme Nomenclature, Classification, Cofactor, Active Site, Specificity and Factors Affecting Enzyme Action, Enzyme Regulation- Enzyme Inhibition (Competitive Inhibition, Uncompetitive Inhibition), Control of Enzyme Quantity, Altering the Catalytic Efficiency of the Enzyme, Enzymes in Clinical Diagnosis and Pharmaceutical Industries

Suggested readings:

- Principles of Biochemistry, A.L. Lehninger, D. L. Nelson, M.M.Cox., Worth Publishing.
- Harper's Biochemistry K. Robert, M.D. Murray, D.K. Granner, P.A. Mayes and V.I. Rodwell, McGraw Hill/ Appleton and Lange.
- Biochemistry (Fifth Edition), Lubert Stryer.
- V.Voet and J.G.Voet, Biochemistry, 3rd edition, J ohn Wiley, NewYork, 2004.
- Jayaram, J Laboratory manual in Biochemistry. Wiley Eastern1981.
- MuP,Plummer DT. Introduction to practical Biochemistry. Tata Mcgraw -Hill Education: 2011

List of Practicals:-

- 1. Qualitative analysis of Amino acids and Proteins.
- 2. Qualitative analysis of Simple sugars and Carbohydrates.
- 3. To estimation of Protein Qualitatively by Folin Lowry Method.

- 4. Qualitative assay of Protein by the Biuret method.
- 5. Qualitative assay of Protein by the Lowry's/Bradford's method.
- 6. Isolation /Extraction of biochemical metabolites (Carbohydrates, Protein and Lipids) from various tissues (plant & animals).
- 7. Estimation of glucose by Benedict's method.
- 8. Estimation of cholesterol by Zak's method.
- 9. Estimation of cholesterol by the method of Crawford
- 10. Estimation of enzyme activity.(salivary amylase/LDH)
- 11. Determine the activity of urease
- 12. Determine the activity of catalase.
- 13. Determine the activity of Alkaline Protease.
- 14. Determine the activity of neutral Protease.
- 15. Estimation of enzyme activity under various conditions –pH, t emperature and substrate.
- 16. Estimation of ascorbic acid / Tocopherol
- 17. Assay of enzyme/hormone by ELISA.
- 18. Enzyme kinetics
- 19. Perform protein isolation by SDS PAGE.

RB10702-MICROBIAL PHYSIOLOGY AND GENETICS

Unit -I: Introduction to microbiology

Microbes and their types, Viruses, Bacteria, fungi and protozoans – Morphology and classification. Abnormal forms of bacteria, archaebacteria, mycoplasma and PPLO, cultivation of bacteria—nutritional requirements of bacteria, physical requirements, different types of media & their preparations. Koch's postulates, Axenic culture, Isolation of pure cultures, maintenance and preservation of the pure cultures. Culture characteristics, bacterial growth kinetics, enumeration of cells by direct and indirect methods.

Unit- II: Control of micro-organisms

Concept of sterilization and disinfection. Physical and chemical methods of microbial control. Chemotherapeutics, susceptibility test (broth procedures and diffusion methods), mode of action of antibiotics, narrow and broad spectrum (Penicillin, ampicillin, sulfonamide, vancomycin, tetracycline, chloramphenicol, antifungals (clotrimazole, fluconazole), antiretroviral (tenofovir, AZT).

Unit-III: Microbial genetics

Molecular classification of microbes, The Basics of microbial genetics, prokaryotic gene organization, The basic principles of microbial DNA, replication, transcription and translation. Microbial regulation of gene expression: the *trp* and *lac* operon.

Unit-IV: Microbial genetic change and viral genetics

Basics of microbial gene transfer: transformation, transduction, conjugation, plasmids, transposons. Viral Genetics Reproductive cycles of bacteriophage, M13 and lambda.

Unit-V: Soil and Agricultural Microbiology

Normal microflora of soil, host parasite interactions, allelochemistry and mechanisms of pathogenesis, agriculturely-important pathogenic microorganisms (bacteria, fungi and viruses), applications of the basic principles of microbiology in effective diagnosis, treatment and prevention of infectious disease.

Suggested readings:

- 1. Microbiology VI Edition, M.J. Pelczar, E.C.S. Chanand N.R. Kreig, Tata McGrawHill.
- 2. General Microbiology, R.Y. Stanier, J.L. Ingraham, M.L. Wheelisand P.R. Painter, Macmillian.
- 3.The microbes—An Introduction to their Nature and Importance, P.V. Vandenmark and B.L.Batzing Benjamin Cummings.
- 4. The Microbial World, RogerY. Stanier, Prentice Hall.
- 5. Microbiology, Tortora, Funkeand Chase, Benzamin & Cummings.

Practicals:-

- 1. Microbial isolation techniques. Isolation of bacteria and fungi.
- 2. Isolation of pure culture from soil and water
- 3. Isolation and maintenance of organisms by plating, streaking and serial dilution methods. Slants and stab cultures. Storage of microorganisms.
- 4. Growth; Growth curve; Measurement of bacterial population by turbidity and serial dilution methods. Effect of temperature, pH and carbon nitrogen sources on growth.
- 5. Establishment of pure cultures-streak, pour and spread plating techniques
- 6. Identification of microbes. Simple, differential, negative staining and spore staining method.
- 7. Establishment of bacterial growth curve/ One step growth curve of bacteria
- 8. Bacteriophage plaque assay to enumerate phage titer.
- 9. Test for *in vitro* antibiosis
- 10. Screening of microbes for the production of enzymes and hormones
- 11. Biochemical and genetic fingerprinting of microbes
- 12. Phylogenetic analysis of microbes
- 13. Microbial preservation techniques-patch plate, slant, water stock, glycerol stock and lyophilization.
- 14. Study of mutations by Ames test.
- 15. Assay of antibiotics and demonstration of antibiotics resistance.
- 16. Biochemical characterization of selected microbes.
- 17. Bacterial transformation.
- 18. Microscopic examination of bacteria, yeast and molds and study of organisms by Gram stain, Acid fast stain and staining for spores.

RB10703T-CELL BIOLOGY

Unit-I: Introduction

Cell types (prokaryotes/ eukaryotes), cell organelles, cell wall, cell membrane, cytoplasmic organelles, structure of nuclear envelope, nuclear pore, complex, transport across envelope, regulation of nuclear import.

Unit-II: Protein trafficking

Targeting proteins to endoplasmic reticulum, signal recognition particle, signal recognition particle receptor, protein folding and processing in ER, protein export from ER, Protein sorting and export from golgi apparatus; SNARE hypothesis; Protein import into Mitochondria, Import and sorting of chloroplast protein.

Unit-III: Cytoskeleton

Structure and organization of cell skeleton; Microfilaments and Microtubule-structure and assembly, actins, myosin muscle contraction, cilia, flagella-structure and function.

Unit-IV: Cell signaling

Cell-cell interaction, modes of cell signaling, steroid hormone receptors, peptide hormones and growth factor, plant hormones, G-protein coupled receptors; receptor –protein tyrosine kinase, c-AMP pathway of signal transduction; c GMP, phospholipids and calcium ions, MAP kinase pathway, JAK – STAT pathway, Integrin signaling, Hedgehog and Wnt pathways.

Unit V: Cell division and cancer biology

Cell Cycle: Interphase and M phase (mitosis and meiosis), Cell cycle regulation, check points in cell cycle; regulators of cell cycle, Apoptosis: intrinsic and extrinsic pathways.

Cancer biology: types of cancer; development of cancer, cells; Oncogenes, protooncogenes, function of oncogene products, tumor suppressor genes, function of tumor suppression gene products, role of oncogene and tumor suppressor gene in development, molecular diagnosis of cancer.

TEXTANDREFERENCES

- Molecular Cell Biology by Bruce Albert
- Molecular Biology by Lodish, Darnell and Baltimore
- Molecular Biology of the gene by Watsonetal 4thed.
- Cell and molecular biology by Gerald Karp
- Cell biology by Pollard and Earnshaw

List of Practical's:-

- 1. To prepare the temporary stained slide of onion bulb peel to study the structure of plant cell.
- 2. To prepare the temporary stained slide of cheek squamous epithelial cells of mouth of Human Beings.
- 3. Preparation and Study of slide of mitosis using from onion root tips squash.
- 4. Schedule for study of mitotic index.
- 5. To determine the abnormal mitotic index.
- 6. Preparation and study of slide for meiosis using young anthers of Allium cepa.
- 7. To determine the meiotic index in the flower bud of Allium cepa.

RB10704T- BIOSTATISTICS AND COMPUTER APPLICATION

A.BIOSTATISTICS

UNIT- I: Descriptive Statistics

Introduction of Statistics, Applications and drawback of Statistics, Concept of variables in biological systems, Collection, classification, tabulation, graphical and diagrammatic representation of numerical data Measures of central tendency: Arithmetic Mean, Median, Mode, Geometric Mean, Harmonic Mean and Quartiles.

Measures of Dispersion: Range, Quartile deviation, Mean deviation, Standard deviation and Coefficient of variation.

Correlation and Regression: Correlation Coefficient, Rank correlation, Regression coefficients, Regression lines (Y on X and X on Y).

UNIT-II: Probability theory and Tests of Significance

Probability: Introduction, Random experiment, Sample space, Events, Definition of Probability, Addition and Multiplication Law of Probability, Conditional Probability, Bayes theorem, Applications of probability. Probability Distributions: Random variables, Binomial distribution, Poisson distribution and Normal distribution, Applications of distributions.

Tests of Significance: Based on t, F, Z and Chi-square distributions.

UNIT-III: Analysis of Variance and Design of Experiment ANOVA:

One-way and Two-way classifications.

Design of Experiment: Principles of Design of Experiment, Completely Randomized Design (CRD), Randomized Block Design, (RBD), Latin Square Design (LSD), Statistical and graphic software-their use in research for data analysis, interpretation and presentation.

B. COMPUTER APPLICATIONS.

UNIT-I: Introduction to computers and Bioinformatics

Software and Hardware, storage and memory devices, input and output devices, of internet and e-mail. Bioinformatics- History, scope and applications.

UNIT-II: Biological databases

EMBL, GENBANK, DDBJ, PIR, PDB, SWISSPROT and TrEMBL. Understanding the structure of each source and using it on the web.

UNIT-III: Sequence alignments

Pairwise sequence Alignments, FASTA and BLAST, Multiple Sequence Alignment Phylogenetic Analysis. Open reading frame.

Protein Secondary structure prediction methods, and homology modeling.

Practicals: Biostatistics.

- 1. Calculate the mean value of given sample.
- 2. Calculate the median of the given sample.
- 3. Find out the mode value of given sample
- 4. To complete correlation of leaf length & breadth of a given leaf sample.
- 5. To perform the t-test for the given data of sample. (Leaves)
- 6. To perform the Chi- Square test for the given data.
- 7. To calculate Standard deviation from the data (Sample).
- 8. Experiments based on probability.
- 9. Draw Histogram, Pie, Graph, Line graph
- 10. Computer based statistical tools.

Bioinformatics:

- 1. To extract protein / nucleotide database of phosphoprotein P of [Swine parainfluenza virus 3]
- 2. To find out and study the human nucleotide sequence records associated with cancer
- 3. To find out the location of particular target gene on human chromosome map
- 4. To study sequence alignment through BLAST
- 5. To study multiple sequence alignment
- 6. To find out protein modelling through MMDB.
- 7. To study how to develop primer (F+R) from given nucleotide sequences

RB10801T-BIOANALYTICALTECHNIQUES

UNIT-I: Chromatography

Principle, types and applications- partition, adsorption, paper, thin layer, ion exchange, molecular sieve, supercritical fluid, gas chromatography and HPLC.

UNIT-II: Electrophoresis

Principle, instrumentation and applications of moving boundary and zonal electrophoresis, including paper and gel (SDS-PAGE and Agarose) electrophoresis, isoelectrofocusing, PFGE and Capillary electrophoresis.

UNIT-III: Centrifugation

Principles of sedimentation & centrifugation, relationship between RCF and RPM, types of centrifuge, differential and density gradient centrifugation (rate zonal and isopycnic).

UNIT-IV: Microscopy

Principles and applications of light microscope, fluorescence, Phase contrast, Darkfield, electron microscopy (TEM and SEM), interference, polarization, inverted and stereomicroscope. Freeze fracture, fixation and staining

UNIT-V: Spectroscopy

Principle, Instrumentation and applications of UV-Visible, IR, NMR, atomic absorption, Fluorescent spectroscopy, X-ray Crystallography and Mass Spectrometry.

UNIT-VI: Radiation Biology

Radioisotope Techniques: Radio-tracers, interaction of radiation with matter, GM counter, Scintillation counters, autoradiography and radioimmunoassay.

List of Practicals:

- 01. Separation of amino acids by paper chromatography.
- 02. Separation of amino acids/ sugars/ lipids by Thin Layer Chromatography.
- 03. Ultra violet absorption spectra of nucleic acids and proteins.
- 04. Determination of molar extinction coefficient of tryptophane / tyrosine.
- 05. Gel filtration of proteins.
- 06. Ion exchange chromatography of amino acids.
- 07. Purification of enzyme by affinity chromatography.
- 08. Subcellular fractionation by differential centrifugation.
- 09. Polyacrylamide gel electrophoresis of proteins.
- 10. Determination of isoelectric point of glycine.
- 11. Estimation of glycine by formal titration.
- 12. Estimation of reducing sugars by Benedict's titrimetric method.
- 13. Estimation of total carbohydrates by anthrone method.
- 14. Estimation of proteins by Lowry and Bradford methods.
- 15. Estimation of ascorbic acid.
- 16. Determination of Iodine value of oils.
- 17. Estimation of cholesterol.

Suggested readings:

- 1.Instrumental Analysis: D.Skoog
- 2.Biophysical Chemistry:David Sheehan
- 3. Principles of Biophysical Chemistry: David Frifelder
- 4. Biophysics: Upadhyay & Upadhyay
- 5.Methods of Instrumental Analysis: Willard
- 6.Principles & techniques of practical Biochemistry, by Wilson /Walker: Wiley Publication (2010)

RB10802T-MOLECULAR BIOLOGY

UNIT-I

Chromatin structure and gene expression: Chromatin structure and transcription. Regulation of chromatin structure, Transcription in prokaryotes and Eukaryotes, Structure of RNA polymerase (Channelin and Channelout). Types of RNA polymerases,

Types of Promoters, initiation, elongation, termination and anti-termination. Initiation factor, role of transcription factors, Regulation of RNA polymerase. Transcription in cell organelles (Mitochondria and chloroplast).

UNIT-II

Post Transcriptional and translational events

RNA processing in eukaryotes: modifications, splicing and splicing machinery, processing of RNA. Editing and amplification. Translation: in Prokaryotes and Eukaryotes. Initiation, elongation, and termination, mRNA localization and stability Modification folding and transport protein. Molecular chaperons in folding, Protein sorting and trafficking using signal proteins,

UNIT-III

RNA interferences and epigenetics

DNA rearrangement, RNAi, regulation of translation, RNA interference, Gene silencing, Epigenetic inheritance and Retrotransposons

UNIT-IV

Omic studies

Omes and Omics, concepts and applications, genome overview at the level of chromosomes (with model organisms as example), strategies for large Scale DNA sequencing. EST and STS, Whole Genome Analysis techniques. Next generation sequencing methods, organization, structure, and mapping of genomes (with model organisms as example) Introduction to proteomics, transcriptomics, metabolomics.

Whole exome analysis.

Laboratory Work

- 1. PCR amplification of genomic DNA.
- 2. Reverse-transcription polymerase chain reaction.

- 3. Western Blot of regulatory protein of cell cycle / apoptosis.
- 4. Preparation of metaphase chromosomes from cultured lymphocytes and cell lines.
- 5. Genetic fidelity of tissue culture plants with RAPD markers.
- 6. Electrocompetent cell preparation.
- 7. Transformation of *E.coli* by electroporation.
- 8. Transformation of S. cerevisiae.
- 9. Mating of S. cerevisiae.
- 10.Genomic DNA isolation from mammalian cells/tissue.
- 11. Total RNA isolation from mammalian cells/tissue.
- 12. Quantification of gene expression by quantitative RT-PCR.
- 13. Histone extraction from mammalian cells.
- 14.SDS-PAGE analysis of histones.

Suggested readings:

- 1. GenesXI,11 th edition (2012), BenjaminLewin, Publisher-Jonesand BarlettInc. USA
- 2. Molecular Biology of the Gene, 6thEdition (2008), James D. Watson, Pearson Education, Inc. and Dorling Kindersley Publishing, Inc. USA
- 3. Molecular Biology, 5th Edition (2011), Weaver R., McGraw Hill Science. USA
- 4. Fundamentals of Molecular Biology,(2009),Pal J.K.and Saroj Ghaskadbi,Oxford University Press. India
- 5. Molecular Biology: genes to proteins,4thedition(2011),Burton ETropp Jones & Bartlett Learning, USA
- 6. Discovering genomics, Proteomics and Bioinformatics (2006) A. Malcoln Campbell, laurie J. Heyer Benjamin Cummings;2nd edition.

RB10803T-IMMUNOLOGY

UNIT-I

Types of immunity: innate, acquired, active and passive, primary and secondary lymphoid organs, antigenantibody Interactions (physical aspects), elements of immune system: T- cells, B-cells, cell mediated subset of T- cells, helper and suppressor cells, markers, third population of lymphocytes, antigen presenting cells, cell mediated and humoral immunity, antibody dependent cell mediated cytotoxicity, natural killer cells.

UNIT-II

Cellular and molecular aspects: nature of antigens, basic structure of antibodies, their function and diversity, antibody classes and biological activity, T-cell receptors, complement system, major histocompatibility complex (MHC), MHC molecules, exogenous and endogenous antigen presentation, lymphokines, regulation of immune response, immunological tolerance.

UNIT-III

Agglutination, Precipitation, Single and double immunodiffusion, Immuno-electrophoresis, ELISA and its various types, Western blotting, Fusion of myeloma cells with lymphocytes, concept of trioma, hybrid-hybridoma and thymoma, applications of monoclonal antibodies

UNIT-IV

Synthetic vaccines, autoimmunity, hyper-sensitivity, tumor immunity, concept of idiotypes and antiidiotypes

Suggested readings:

- 1. Immunology: Janis Kuby
- 2. Essentials of Immunology: Ivan Roitt
- 3. Cellular and Molecular Immunology: Abul KAbbas, Andrew HLichtman and S Jordan.
- 4. Immunology: An Introduction: Ian R Tizard
- 5. A Hand book of Practical Immunology: G P Talwar

List of practicals:

- 1. To study the techniques of immunization and generation of antibodies.
- **2.**To perform differential leukocyte count of human blood.
- 3. Isolation of IgG from human serum by affinity chromatography using protein A column.
- **4.**To perform precipitation tests (a) ring test (b) slide test in solution given an antigen and antibody.
- **5.** To perform precipitation reactions in gel by Ouchterlony Technique given an antigen and antibody (double immune diffusion).
- **6.** To perform single radial immune diffusion (Mancini's Technique) using an antigen and antibody.
- **7.**To perform immune electrophoresis given an antigen and antibody.
- **8.** To perform rocket immune electrophoresis on given antigen and antibody.
- **9.** To perform ELISA.
- 10. To perform rapid Agglutination Test for detection of RA factors in serum.

RB100804-NANOTECHNOLOGY

UNIT-I

Introduction: Definition, interdisciplinary nature, learning from nature (linear and rotary molecular motors, abalone shells) and scope.

Bio-nanostructures: Protein based nanostructures self-assembly engineered nanopores, protein micro-arrays, magnetosomes, bacteriorhodopsin and their application.

DNA based nanostructures: DNA-protein nanostructure, DNA-templated electronics, DNA Gold nanoparticle conjugates-chip based DNA detection, DNA Nanostructures for mechanics and computing, nanoparticles as non-viral transfection agent.

UNIT-II

Silica nanoparticles for analytical microbial biofilms structure and applications, artificial cells. Nanostructured fluids and soft material: Applications in drug solubilization and delivery, Nutraceuticals enhanced oil recovery, antimicrobial and cosmetic nanoemulsions, food colloids, templating of nanoparticle.

UNIT-III

DNA-Nanotechnology: Structural DNA assembly, nanopore DNA sequencing, DNA coupled to carbon nanotubes, DNA-modified surfaces, polyelectrolyte behavior in DNA, self-assembling toroidal nanoparticles. Applications of nanoparticles: Nanoparticles for biological assays, as drug delivery vehicles and as contrast agent.

UNIT-IV

Application of nanotechnology/ nanobiology/ nanotechnology in bio-mineralization, medicine and surgery (stem cell biology, artificial organs, tissue engineering, cardiology and cardiac surgery, organ transplantation and cancer).

List of practicals

- 1. Synthesis of metal oxide nanoparticles using sol gel method.
- 2. Extracellular synthesis of silver nanoparticles by using microorganism
- 3. Synthesis of metal oxide nanoparticles using biological process.
- 4. Preparation of nanocomposites from
- 5. Characterization of Nano materials using analytical techniques.
- 6. Biological activity of Nano materials.
- 7. Synthesis of Fe2O3, AuCl2 and AgO2 nanoparticles by chemical method.
- 8. Synthesis of semiconductor nanoparticles by chemical method.
- 9. Synthesis of nanoparticles using biological process (2-3 methods).
- 10. Detection of nanoparticles in colloidal solutions using UV-Vis absorption Technique.
- 11. Size determination of nanoparticles using laser beam.
- 12. Biological sample preparation for SEM
- 13. Antimicrobial activity of nanoparticles Agar-diffusion assay, Viable cell count, Cell membrane integrity and Flow cytometry.
- 14. Cytotoxicity assessment of nanoparticles-Peripheral blood mononuclear (PBMC) culture.
- 15. Synthesis of nanoparticles using fungus/ bacterium/plant extract.

Suggested Readings:

- 1.A Laboratory Course in Nanoscience and Nanotechnology (2014). Ed. Gerrard Eddy Jai Poinern.CRC Press, USA.
- 2. Nanobiotechnology Protocols (2005). Eds. Rosenthal, Sandra J, Wright, David. Springer's Humana Press, USA.
- 3. Nanobiotechnology: Concepts and Applications in Health, Agriculture, and Environment (2019). Eds. Rajesh Singh Tomar, Anurag Jyoti and Shuchi Kaushik. CRC Press, USA.
- 4. Nanobiotechnology. Concepts. Applications & Perspectives: CM Niemeyer and CA Mirkin, Wiley VCH-Verlag.\
- 5.From Biology to Biotechnology& Medical Applications: EBauerlin, Biomineralization- Wiley VCH-Verlag.
- 6. Nano & Microscience, Engineering Technology and Medical Series: Lyshevski, Sergey Edward, CRC Press.
- 7. Nanostructures and Nanomaterials: GCao, Imperial College Press.
- 8. Nanoscale Technology in Biological Systems: RS Greco, FB Prinz and R L Smith. CRC Press.

SEMESTER-IX

RB100901-ANIMAL BIOTECHNOLOGY

UNIT I

Introduction, brief history and terminology, source of some important mammalian cell lines. Balanced salt solutions and simple growth media, serum and its quality, medium sterilization.

Basic techniques of scaleup of animal cell culture: roller bottles modification of roller bottles, multiunitsystemandconceptofbioreactorsincludinghollowfibersystem & their application.

UNIT-II

Preservation and maintenance of animal cell lines, cryo-preservation and transport of animal germplasm (i.e. semen, ova and embryos). Production of monoclonal antibodies by hybridoma technique, scaleup (*in vivo* and *in vitro*), brief concept of trioma and thymoma.

UNIT-III

Concept of stem cells, Embryonic and adult stem cells, tissue engineering and its application. Gene cloning techniques for mammalian cells, cloning in mammalian cells. Transgenic animals, *in vitro* fertilization and embryo transfer. Molecular biological techniques for rapid diagnosis of genetic diseases and gene therapy.

UNIT-IV

Chemical carcinogenesis, transfection, oncogenes and antioncogenes. Cell synchronization methods and their applications, Concept of idiotype/ anti-idiotype and their applications.

Practical:

- 1. Extraction and estimation of DNA from blood
- 2. Extraction and estimation of DNA from spleen
- 3. Extraction and estimation of DNA from muscle tissue
- 4. Cell viability test
- 5. Blood cell smear formation and staining
- 6. Separation of serum and plasma from blood.

Suggested books:

- 1. Animal Cell Biotechnology: R E Spier and J B Griffiths
- 2. Living Resources for Biotechnology-Animal cells: A Doyle, R Hay and B E Kirsop
- 3. Animal Biotechnology: Murray Moo-Young
- 4. Animal Cell Biotechnology-Principles and Practices: M Butler.
- 5. The Animal Cell Culture and Technology: M Butler.
- 6. Culture of Animal Cells: R T Freshney.

RB100902-PLANT BIOTECHNOLOGY

UNIT-I

Introductory history, scope and application of plant biotechnology. Plant cell and tissue culture media, plant growth regulators in tissue culture-their use and preparation. Cellular totipotency, cyto-differentiation and organogenesis; somatic embryogenesis; transfer and establishment of whole plants in soil (acclimatization & hardening); Designing and erection of polytunnels and greenhouses.

UNIT-II

Initiation of aseptic culture techniques; *In-vitro* and *in vivo* pollination and fertilization; single cell and cell suspension culture, callus culture, embryo culture and embryo rescue; protoplast culture and somatic hybridization, selection of hybrid cells; symmetric and asymmetric hybrids, cybrids.

UNIT-III

In vitro clonal propagation and large-scale production of plants through micropropagation. Prospects and problems, meristem tip culture, shoot tip culture and shoot tip grafting. Doubled haploid production through distant hybridization, Production of haploid plants through androgenesis (anther and pollen culture) and gynogenesis (ovary and ovule culture) and their utilization.

UNIT-IV

Production of useful bio-chemical substances through tissue culture system, Scale-up through bio-reactors. Bioinsecticides, biopesticides and biofertilizers. Gene transfer in nuclear genome and chloroplasts; Agrobacterium- mediated gene transfer, direct gene transfer. Transgenic plants: insect resistance, virus resistance, abiotic stress tolerance, longer shelf life (including strategies for suppression of endogenous genes), male sterility, enhanced nutrition (golden rice), edible vaccines. Preservation of plant genetic resources: Germplasm collection and conservation.

Suggested books

- 1. Plant Tissue Culture Applications and Limitations: S S Bhojwani.
- 2. Genome Organization and Expression in Plants: CJ Lever.
- 3. Plant Cell Culture –A practical Approach: R A Dixon & Gonzales.
- 4. Principles of Plant Biotechnology- An Introduction to Genetic Engineering in Plants: Mantell, Mathews & Mavkee.
- 5. Plant Cell Biology- A Practical Approach: N Harris & KJ Oparke.

Practicals:

- 01. Preparation of media for plant tissue culture (MS and B5).
- 02. Meristem / bud culture, shoot multiplication & rooting
- 03. Somatic embryogenesis
- 03. Plantlet acclimatization
- 03. Establishment of callus cultures from carrot cambial tissue.
- 03. Establishment of cell cultures and plating.
- 04. Embryo culture of maize/ crotalaria.
- 05. Organogenesis and regeneration of plants from tobacco explants.
- 06. Anther culture and production of haploids.
- 07. Micropropagation using suitable system: Potato/solanum's
- 08. Enzymatic isolation of protoplast and culture.

- 09. Polyethylene glycol (PEG) mediated fusion of protoplasts.
- 10. Agrobacterium culture and transformation.
- 11. Reporter gene assay (GUS)
- 12. Extraction of DNA from plant.
- 13. Estimation of plant DNA by Agarose gel electrophoresis and Spectrophotometer.

RB100903T-FOOD BIOTECHNOLOGY

Unit -I

Food Microbiology

Importance and Significance of Microbes in Food Science Sources of Microorganisms in Foods and Their Effective Control FactorsAffectingGrowthandSurvivalofMicroorganismsinFoods-Intrinsic Factors and Extrinsic Shelf Life-Calculation of Shelf Life, Shelf life Requirements and Simulation Microbial Toxins- Bacterial Toxins, Fungal Toxins, Food Borne intoxications and Infections

Unit -II

Food Chemistry

Flavour-Flavourmatics/ Flavouring Compounds, Sensory Assessment of Flavour, Technology for Flavour Retention

Pigments-Technology for Retention of Natural Colours of Food Stuffs, Food

Colorants - Popular Colors Used in Food Vitamins-Requirements, Allowances

and Retention of Vitamins

Minerals-Requirements, Allowances and Retention of Minerals

Unit- III

Processing of Food

Cereals , Pulses and Oilseed Products-Milling and Processing

Dairy Technology-Stages of processing and Other Products

Fruits and Vegetables-Processing and Preservation Membrane Technology in Food Processing

Unit-IV

Food Preservation

Low Temperature-Cool Storage and Freezing Definition, Types of Freezing– Slow Freezing, Quick Freezing, Thawing High Temperature -Commercial Heat Preservation Methods Moisture Control-Drying and Dehydration, Evaporation Irradiation-Uses of Radiation Processing in Food Industry, Concept of Cold Sterilization, Preservation by chemicals and Non-thermal preservation process

Unit -V

Food Packaging and Safety

Introduction-Packaging Functions and Requirements-Printing, Barcodes and Other Marking - Labelling Laws

Food Packaging Materials- Paper and Paper-Based Materials, Corrugated Fibre Board (CFB), Plastics, Biodegradable Plastics, Edible Packaging, Metal Packaging, Glass

Packaging of Foods-Packaging of Fresh Produce and Processed Foods, Aseptic Packaging, Advances in Food Packaging

Quality Assurance-Microbiological Quality Standards of Food, GMP, FSSAI, FDA, EPA, HACCP, ISI, ISO, E-number, GMO Food.

List of Practicals:

- 1. Fungal spore/Yeast cells count
- 2. Isolation, screening and optimization of conditions for production:
- 3. Solid state fermentation: enzymes, alcohol
- 4. Submerged fermentation: enzymes, exopolysaccharide, alcohol, organic acids and antibiotics

- 5. Ammonium sulphate precipitation method for enzyme purification
- 6. Electrophoretic separation of proteins by PAGE: SDS and NATIVE
- 7. Estimation, recovery and purification of fermentation products- Antibiotics, Organic acids, Alcohol, Exopolysaccharide.
- 8. Rheological study of culture broth by Brookfield viscometer
- 7. Influence of different parameters on immobilisation of cells and enzymes
- 8. Scale up study
- 9. Qualitative and quantitative analysis of carbohydrates and proteins in food
- 10. Preparation and evaluation of cheese or fermented product
- 11. Determination of fat content in milk
- 12. Estimation of vitamins- vitamin A, C and riboflavin
- 13. Determination of aflatoxin in food
- 14. Tests for pesticidal residues in food

Suggested Books

- 1. Adams, M.R. Moss, M.O. Food Microbiology, U.S.A.: Royal Society of Chemistry, 2000.
- 2.Bhatia. S.C. Food Biotechnology, WPI Publishing India, 2017.
- 3.Doyle, M.P.,Buchanan, R.L. Food Microbiology: Fundamentals and Frontiers.U.S.A.ASM, 2012.
- 4.SinoshSkariyachanandAbhilashM. Introduction to Food Biotechnology, CBS, India 2012
- 5. Garbutt, J. Essentials of Food Microbiology, U.S.A.: Hodder, 1997.
- 6.George, B. J. Basic Food Microbiology. U.S.A.: Springer, 1989.
- 7. Foster WM Food Microbiology, CBS, 2005.
- 8.Joshi, V.K., Pandey. A Biotechnology: Food Fermentation Microbiology, Biochemistry and Technology. India: Educational, 1999.
- 9. Ravishankar Rai V. Advances in Food Biotechnology. Wiley-Blackwell, U.S.A. 2015.

RB100904T-PHARMACEUTICAL BIOTECHNOLOGY

Unit I:

Introduction

Introduction and History, DNA, RNA, post-translational processing, metabolic enzymes

involved in nucleic acid synthesis, G-protein coupled receptors (monomeric transmembrane

proteins), small molecule receptors, ligand-gated ion channels (oligomeric transmembrane

proteins), transporters (multi-transmembrane proteins).

Pharmaceutical Products: Therapeutic categories such as laxatives - analgesics - non steroidal

contraceptives - external antiseptics - antacids and other, antibiotics - biological-hormones-vitamins with respect to system.

Unit II:

Drug discovery methods

Meaning of drugs, Drug Discovery Process, biological activity directed and other types of screening, natural products, combinatorial chemistry; General overview of validation techniques, Methods of Drug Discovery and development, QSAR and SAR. Concepts of Bioavailability, Process of drug absorption, Pharmacokinetic processes, Timing for optimal therapy, Drug delivery considerations for the new biotherapeutics.

Pharmaceutical Development: Introduction to drug regulations, pre-clinical and clinical trials.

Unit III:

Pharmacology of drugs

Physicochemical Properties in Relation to Biological Action, Effects of route of administration, Drug Targets, Validation techniques of Pharmaceutical targets, Pharmacokinetics and pharmacodynamics of drugs, Drug Toxicity.

Basic terminologies in drug delivery and drug targeting, Doses forms, Various routes of administration of drugs (just introduction), Strategies for enhanced therapeutic efficacies (Basic principles) DNA vaccines, Vaccines & Monoclonal antibody based pharmaceuticals, Antibiotics, Characterization and Bioanalytical aspects of Recombinant proteins as pharmaceutical drugs.

Unit IV:

Formulations & Regulations

Formulation of Biotechnological Products, Drug Delivery, Examples of some Biotechnological products in clinical development.

Role of FDA, ICH Guidelines, The Regulation of Pharmaceutical Biotechnological Products & Ethical Issues.

List of Practicals

- 1. Qualitative analysis of plant based drugs
- 2. Isolation of drugs by HPTLC (flavonoids /alkaloids)
- 3. Quantitative analysis of a drug (aspirin/ paracetamol) by spectrophotometer/HPLC
- 4. Quantitative assay of drug/metabolite by ELISA
- 5. In silico docking analysis of drug analogs
- 6. In vitro bioactivity assay-antioxidant activity/antidiabetic activity
- 7. Different routes of drug administration in rodents (Demo)
- 8. Evaluation of anti-inflammatory/analgesic effect of a drug (Demo)

- 9. Processing of biological fluids /tissues for biochemical assays
- 10. Isolationandprocessingofbiologicaltissuesforhistopathologicalanalysis

Suggested Reading:

- 1. A Practical Guide to Pharmacological Biotechnology Authors: Patra, J.K., Das, S.K., Das, G., Thatoi H. Springer Publications eBookISBN978-981-13-6355-9
- 2. Laboratory Hand book on Biochemistry S. Shanmugam, T. Satish Kumar, Paneer Sevam, PHI Learning Pvt. Ltd. New Delhi 2010
- 3. Screening Methods in Pharmacology1s t Edition Volume II Editors: Robert Turner Peter Hebborn Elsevier Publications 1971 eBook ISBN: 9781483264233

Drug Delivery and Targeting, A.M. Hillery, A.W. Lloyd and J. Swarbrick, Harwood Academic Publisher.

- 4. Pharmaceutical Dosage Forms and Drug Delivery Systems, H.C.Ansel ,L.V. allen and N.G. Popovich, Lippincott Williams and Wilkins Publisher
- 5. Applications of Targeted Nano Drugs and Delivery Systems, Shyam Mohapatra, Shivendu Ranjan, Nandita Dasgupta, Raghvendra Mishra and Sabu Thomas (EDs.), Elsevier, 2019. 7. Introduction to Biophysical Methods for Protein and Nucleic Acid Research, J.A. Glasel And M.P. Deutscher, Academic Press.
- 8.GaryWalsh.(2007).PharmaceuticalBiotechnology-ConceptsandApplications,John Wiley &Sons Ltd.,
 - 9. Laurence Brunton, Bruce A Chabner, Bjorn Knollman. (2013). Goodman & Gillman's. The

Pharmacological Basis of Therapeutics, 12th Edition, McGraw-Hill Education

10.Roop K Khar, Vyas SP, Farhan J Ahmad, Gaurav K Jain. (2013). Lachman/Liebermans: TheTheory

and Practice of Industrial Pharmacy,4thEdition, CBS Publishers and Distributors.

11.BararFSK.(2013).TextbookofPharmacology,1stEdition,S.Chand Publishing.

RB101001T-RECOMBINANT DNA TECHNOLOGY

UNIT-I

Introduction and Enzymes in Recombinant DNA Technology: Introduction to Genetic Engineering and Recombinant DNA Technology.

Restriction Modification Systems-Types and Nomenclature and Restriction Enzymes TYPE I, II, III

DNA Ligase-Properties and Specificity, Other Enzymes Used in Recombinant DNA Technology -S1Nuclease, BAL31Nuclease

DNA Polymerase, Polynucleotide Kinase, Phosphatase, Reverse Transcriptase-Activity and Mode of Action

UNIT-II

Plasmids and Vectors: Plasmids-Properties, Incompatibility, Isolation and Purification Techniques Plasmid Vectors and their Properties, Copy Number, pBR322, pUC, pGEM3Z–its Construction and Derivatives, Single Stranded Plasmids

Bacteriophage lambda (λ) as a Vector-Essential Features, Organization of Genome, General Structure, Rationale for Vector Construction, Cosmids, Phasmids, Fosmids, Phagemids Filamentous Phage Vectors, L Zap, L Blue Print Vectors, Shuttle Vectors, Expression Vectors, Promoter Probe Vectors, Vectors for Library Construction, Linkers, Adaptors, Homopolymer Tailing

UNIT-III

Expression Vectors: Expression Vectors-Expression of Foreign DNA in Bacteria-Fusion Protein and

in Pichia sp. Expression System YACs, BACs, PACs, MACs and HACs Shotgun Cloning-Genomic Library and cDNA Library Construction-Marker Genes Recombinant Selection and Screening

UNIT-IV

Sequencing and Molecular Mapping: DNA Sequencing and Polymerase Chain Reaction-its Principle, Type and Applications, Site Directed Mutagenesis

Molecular Markers and its Applications-RFLP, RAPD, AFLP, VNTR, STS, SSCP, SSR, CAPS, SCAR.

Molecular Mapping of Genome-Genetic and Physical Maps, Chromosome Walking

UNIT-V

Applications in Industrial and Healthcare: Modern Biotechnology–Products Using Gene Cloning–Monoclonal Antibodies, Insulin, Growth Hormones, Vaccines.

Gene Therapy for Inherited Disorders and Neoplastic Disorders Genetically Modified Organisms in Industry–Pseudomonas sp., Bacillus thuringiensis.

PRACTICALS

- 1. Isolation of chromosomal DNA from plant cells
- 2. Isolation of chromosomal DNA from *E.coli*
- 3. Qualitative and quantitative analysis of DNA using spectrophotometer
- 4. Plasmid DNA isolation
- 5. Restriction digestion of DNA
- 6. Transformation of competent cells.
- 7. Demonstration of PCR
- 8. Electrophoretic separation of plasmid by agarose gel electrophoresis
- 9. Quantification and quality checking by UV spectrophotometry and electrophoresis
- 10. Restriction analysis and construction of restriction map of plasmid
- 11. Preparation of competent E.coli cells, Construction of recombinant plasmid
- 12. Genetic Transformation of E.coli with a recombinant plasmid
- 13. Screening transformed cells for the presence of recombinant plasmid and gene 8. Transformation frequency and cloning efficiency.

RB0101002 - MEDICAL BIOTECHNOLOGY

UNIT-I:

Modern Immunological Therapy: Kinetics of immune response and memory; Hybridoma technology; production and purification of monoclonal antibodies; Antibody engineering, Antibody as in vitro and in vivo probes; Immunotoxins, Immunodiagnostics and Immunotherapeutics. Immunoassay: solid immunoassay & their chemistry, Immunocytochemistry, Immunohistochemistry, Immunoediting, Immune surveillance theory.

UNIT-II

Molecular Oncology: Detection of recognized genetic aberrations in clinical samples; types of

cancer causing alterations revealed by next generation sequencing of clinical isolates; predictive biomarkers for personalized oncotherapy of human disease such as chronic myeloid leukemia, colon, breast, lung cancer and melanoma as well as matching targeted therapies with patients and preventing toxicity of standard systemic therapies; Tumor evasion of the immune system, Cancer immunotherapy.

UNIT-III

Commercial Immunodiagnostic kits for common diseases: Dengu, HIV/AIDS, Chikungunya, ELISA kit, Rapid diagnostic test kit, BCG, Typhoid.

UNIT-IV

Common Vaccine developement: Licensed vaccines, Viral Vaccines (Poliovirus vaccine inactivated and Live, rabies vaccines, Hepatitis A& B vaccines), Bacterial Vaccine (Anthrax vaccines, Cholera vaccines, Diphtheria toxoid), Parasitic vaccine (Malaria Vaccine).

UNIT-V

Vaccine Production: The vaccine industry, vaccine manufacturing, Evolution of adjuvants across the centuries, New generation vaccines (bacterial, viral), Edible vaccines, Vaccine additives and manufacturing residuals, Regulation and testing of vaccines.

List of Practicals

- 1. Identification and characterization of selected medically important pathogens Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus pneumoniae and Acinetobacter baumannii
- 2. Culturing of single cell protein (SCP) (Spirullina)
- 3. Ammonium sulfate precipitation of parasite (cysticsacrosis)antigen
- 4. Quality control of antibodies -HPLC
- 5. Introduction and use of various genome databases.
- 6. Similarity searches using tools like BLAST and interpretation of results
- 7. Multiple Sequence alignment using Clustal W
- 8. Phylogenetic analysis of protein and nucleotide(16S)sequences
- 9. Role of bioinformatics in drug development computer assisted drug designing and computer based ligand and Receptor interaction
- 10. Genetic and biochemical analysis of novel molecules.

Suggested Readings:

- 1. Riott I M (2003). Essentials of Immunology. Blackwell Scientific Publishers, London.
- 2. Murray PR, Pfaller MA, Tenover FC and Yolken RH (2007). Clinical
- 3. Microbiology. ASM Press.
- 4. Tizard Ian R (2009). Immunology. An introduction, 4th Edition.
- 5. Kenneth. J. Ryan (2010) Sheris's Medical Microbiology, Mc Graw Hill.
- 6. Kindt, Goldsby and d Osborne (2013). Kuby Immunology. MacMillan Higher Education.
- 7. Willey J, Sherwood L. and Woolverton C (2014). Prescott's Microbiology, 9th edi McGraw Hill.
- 8. Greenwood D (2015). Medical Microbiology, 18th Edition, Elsevier
- 9. Bernard R.Glick, Terry L.Delovitch, Cheryl L.Patten. Medical Biotechnology, ASM Press. 2014

RB101003-BIOENTREPRENUERSHIP

UNIT-I

Intellectual Property Rights: IPRs – Implications for India, WTO, WIPO, GATT, TRIPS Patenting and the Procedures Involved in the Applications for Patents and Granting of Patent. Compulsory Licenses, Patent Search. Special Application of Patent Laws in Patenting of Living Organisms, Plant Breeders Rights, Legal Implications, Traditional Knowledge,

Commercial Exploitation, Protection.

UNIT-II

Ethical Issues in Plant and Animal Research: Ethics-Regulations on Field Experiments and Release of GMO (Genetically Modified

Organisms), International and Indian Regulatory Authority – BRAI, Labeling of GM (Genetically Modified) Foods

Impact of Gene Cloning, Legal, Social and Ethical Issues in Organ Transplantation

UNIT-III

Ethical Implications of Human Genome Project: Ethical Implications of Human Genome Project – International Ethical and Legal

Issues Connected to HGP

Human Fetal Sex Determination - Implications in India Genetic Study on Ethnic Races

UNIT-IV

Entrepreneurship: Introduction, Concept and Theory, Entrepreneurial Traits and Motivation Nature and Importance of Entrepreneurship in India, Promoting Entrepreneurship, Biotech Company Roadmap, Legal, Regulatory and Other Business Factors Barriers in Entrepreneurship, Agreements, Valuation and Business Concerns

UNIT-V

Entrepreneurship Strategies: Funding of Biotech Business, MSME and Technology Incubator Potential Entrepreneurship Activities in Biotechnology, Product Development, Marketing, Role of Knowledge centers and Research and Development (Knowledge Centers like Universities and Research Institutions, Role of Technology and Upgradation) Biotech Parks, Biotechnology Industries in India and the Potential Job Opportunities

List of Practicals:

- 1. Project designing and writing.
- 2. Review the literatures of accepted patents.
- 3. Development of creative ideas for commercialization of technology
- 4. Planning of establishing a hypothetical biotechnology industry in India

Suggested Books

Butler Gerard M. and Harris Antony. Bioethics guide to Pharmaceutical Manufacturers. U.K.: Medicines Control Agency, 2002.

Butler M. Animal Cell Culture and Technology. New Delhi: Bios International, 2000. Damien Hine and John Kapeleris. Innovations and Entrepreneurship –An international

perspectives. U.K.: Edward Elgar, 2006.

Jeffery M. Smith. Seeds of Deception U.S.A: Chelsca Green, 2003.

Thomas Brenner and HolgerPatzelt. Handbook of Bio-Entrepreneurship. U.S.A.: Springer, 2008

Verma and Agarwal. Intellectual property Rights. New Delhi: I. K. International, 1992

RB101004-CLINICAL BIOTECHNOLOGY

UNIT-I

Drug discovery and Preclinical toxicology: Pre-Clinical toxicology: General Principals, Systemic toxicology, (Single dose and repeat dose toxicity studies), Carcinogenicity,

Mutagenicity Teratogenicity, Reproductive toxicity, Local toxicity, Genotoxicity, animal toxicity requirements

UNIT II

Introduction to Clinical trials: Introduction to clinical trials, Historical guidelines in clinical research (Nuremberg code, Declaration of Helsinki and Belmonte report), ICH-GCP guidelines (E6-R1), Phases of clinical trials

UNIT-III

Clinical study design: Clinical study methodology and regulations: Principles, types (single blinding, double blinding, open access, randomized trials and their examples), Design of protocol, CRF, e-CRF, IB, ICF and preparation of trial reports, Regulations involved (ICMR guidelines) and ethics.

UNIT-IV

Medical Writing: Medical Writing- Literature search and medical articles, contract writing, publication, abstracts, bibliography, clinical study reports, principles and softwares in CDM (Clinical Data Management)

List of Practicals:

1.Estimation of Blood glucose by GOD-POD method

2.Liver Function Test: Estimation of serum SGOT

3.Liver Function Test: Estimation of serum SGPT