

**Department of Biotechnology  
Institute of Biosciences and Biotechnology  
Chhatrapati Shahu Ji Maharaj University**

**M.Sc. Syllabus Biotechnology  
M.Sc.I<sup>st</sup> Semester**

<b>Paper</b>	<b>Name of the Paper</b>	<b>Maximum Marks</b>
MBT-101	Cell and Developmental Biology	100
MBT-102	General Biochemistry	100
MBT-103	Biophysical Chemistry and Techniques	100
MBT-104	Fundamentals in Biostatistics and Biomathematics	100
MBT-105	Practical	100

**M.Sc. II<sup>nd</sup> Semester**

<b>Paper</b>	<b>Name of the Paper</b>	<b>Maximum Marks</b>
MBT-201	Molecular Biology and Genetics	100
MBT-202	Microbiology	100
MBT-203	Physiology and Metabolism	100
MBT-204	Computational Biology and Bioinformatics	100
MBT-205	Practical	100

**M.Sc.III<sup>rd</sup> Semester**

<b>Paper</b>	<b>Name of the Paper</b>	<b>Maximum Marks</b>
MBT-301	Cellular and Molecular Immunology	100
MBT-302	Principles of Genetic Engineering	100
MBT-303	Plant Biotechnology and Tissue culture	100
MBT-304	Enzymology and Enzyme Technology	100
MBT-305	Practical	100

**M.Sc.IV<sup>th</sup> Semester**

<b>Paper</b>	<b>Name of the Paper</b>	<b>Maximum Marks</b>
MBT-401	Animal Cell Culture, Medical and Microbial Biotechnology	100
MBT-402	Genomics, Proteomics, Intellectual Property rights, Product Regulation and Biosafety	100
MBT-403A	Industrial Biotechnology	100
	OR	
MBT-403B	Environmental Biotechnology	100
	OR	
MBT-403C	Drug Discovery and Development	100
	OR	
MBT-403D	Nanobiotechnology	100
MBT-404	Project Viva	200

**M.Sc. BIOTECHNOLOGY FIRST SEMESTER**

**MBT--101**

**Paper First**

**Cell and Developmental Biology (Max. marks: 100)**

**Unit I:** Structural organization and function of cell and cell organelles; Structure and function of membrane; Cell division and cell cycle (Mitosis and meiosis-Steps, regulation and control of cell cycle); concepts related to compartmentalization in eukaryotic cells; stem cells, their differentiation into different cell types and organization into specialized tissues; cell-ECM and cell-cell interactions: Cellular communication; general principles of cell communication, cell adhesion and roles of different adhesion molecules, gap junctions, extracellular matrix, integrins, Actin-binding proteins and their significance; Extracellular matrix in plants and animals.

**Unit II:** Molecular mechanisms of membrane transport- Transport of proteins and molecular chaperones; Protein stability; Protein turnover and degradation, nuclear transport, transport across mitochondria and chloroplasts; intracellular vesicular trafficking from endoplasmic reticulum through Golgi apparatus to lysosomes/cell exterior. Cell signaling: Cell surface receptor, Hormones and receptors, Signaling through G-protein coupled receptors, Signals and second messengers; signal transduction pathways, regulation of signaling pathways, bacterial and plant two-component systems, bacterial chemotaxis and quorum sensing; Programmed cell death, aging and senescence.

**Unit III:** Genome instability: Mutations, proto-oncogenes, oncogenes and tumour suppressor genes, physical, chemical and biological mutagens; types of mutations; intra-genic and inter-genic suppression; transpositions- transposable genetic elements in prokaryotes and eukaryotes, role of transposons in genome; viral and cellular oncogenes; tumor suppressor genes; structure, function and mechanism of action; activation and suppression of tumor suppressor genes; oncogenes as transcriptional activators.

**Unit IV:** Basics of development: Potency, induction, commitment, specification, competence, determination and differentiation; morphogenetic gradients; cell fate and cell lineages; stem cells and their properties; transdifferentiation; genomic equivalence and the cytoplasmic determinants; imprinting; mutants their analysis.

Gametogenesis: fertilization and early development; Differentiation of germ layers; Cellular polarity; Maternal gene effects; Zygotic gene effects; Homeotic gene effects in *Drosophila*; Embryogenesis and early pattern formation in plants.

**Unit V:** Morphogenesis and organogenesis in animals: axes and pattern formation in *Drosophila*; Cell lineages and developmental control genes in *Caenorhabditis elegans*;

Differentiation of neurons, post embryonic development- larval formation, metamorphosis; environmental regulation of normal development; sex determination.

### **Texts/References**

1. Lodish et al., Molecular cell Biology, 4th Edition, W.H. Freeman & Company, 2000.
2. Smith & Wood, Cell Biology, 2nd Edition, Chapman & Hall, London, 1996.
3. Watson et al., Molecular Biology of the gene, 5th Edition, Pearson Prentice Hall. USA, 2003.
4. B. M. Turner, Chromatin & Gene regulation, 1st Edition, Wiley-Blackwell, 2002.
5. Benjamin Lewin, Gene IX, 9th Edition, Jones and Barlett Publishers, 2007.

## **MBT--102**

### **Paper Second**

#### **General Biochemistry (Max. marks: 100)**

**Unit I:** Structure of atoms, molecules and chemical bonds; Structure of water and its physico-chemical properties- ions interaction; Significance of weak acids and bases; pH and buffers; colligative properties of solution- freezing point depression, boiling point elevation, vapor pressure lowering, and osmotic pressure, Unit of concentration.

**Unit II:** Carbohydrates: Classification, structures, characteristics and functions of simple and complex carbohydrates; Structure and general function of amino sugars, blood sugar, sugar nucleotides and mucopolysaccharides.

**Unit III:** Proteins: Basic structure and functions of amino acids and proteins; Secondary, tertiary and quaternary structure of proteins; Conformation of proteins (secondary structure, domains, motif and folds-Ramachandran plot), Protein folding; Interactions stabilizing the proteins (Vander Waals, hydrogen bonding, electrostatic, hydrophobic interaction); Protein structure evolution; Structure-function relationships of some model proteins like ribonuclease A, myoglobin, hemoglobin, chymotrypsin, muscular proteins.

**Unit IV:** Lipids: Fatty acids general formula; nomenclatures and properties, lipid classification- simple and complex, general structure and function of major lipid sub class acyl glycerol, phosphoglycerides, sphingolipids, waxes, terpenes, steroids and prostaglandins; Structure and function of membrane: Structure of model membrane, organization of lipid bilayer and membrane protein; Specific properties as- osmosis, diffusion, ion movement and channels, active transport, membrane pumps, mechanism and regulation of intracellular transport, membrane-electrical properties). Nucleosides, nucleotides, nucleic acids - structure, diversity and function; sequencing; Brief overview of central dogma; Conformation of nucleic acids (helix (A, B, Z), t-RNA, micro-RNA).

**Unit V:** Vitamins- Structure, properties and functions including biochemical reactions and deficiency symptoms; Hormones- Properties and function of plant and animal hormones.

**Texts/References**

1. V.Voet and J.G.Voet, Biochemistry, 3rd edition, John Wiley, New York, 2004.
2. A.L. Lehninger, Principles of Biochemistry, 4th edition, W.H Freeman and Company, 2004.
3. L. Stryer, Biochemistry, 5th edition, W.H. Freeman and Company, 2002.

**MBT-103**

**Paper Third**

**Biophysical Chemistry and Techniques (Max. marks: 100)**

**Unit I:** Properties of Biomolecules-mass, density, charge, PI, absorption/emission of light. Some basic Techniques- concept of buffers; Introduction to detergents and membrane proteins; Dialysis, Ultrafiltration and other membrane techniques; Some advance techniques: Protein crystallization; Theory and methods; API-electrospray and MALDI-TOF-and ESI-Mass spectrometry.

**Unit II: Chromatography Techniques:** Partition coefficient; General technique of absorption and partition chromatography; TLC and Paper chromatography; Chromatographic methods for macromolecule separation - Gel permeation, Ion exchange, Hydrophobic, Reverse-phase and Affinity chromatography; HPLC and FPLC; GLC; Criteria of protein purity.

**Unit III: Electrophoretic techniques:** Principle- Theory and application of Polyacrylamide and Agarose gel electrophoresis; Gradient electrophoresis; Capillary electrophoresis; 2D Electrophoresis; Disc gel electrophoresis; Pulsed field gel electrophoresis.

**Centrifugation:** Basic principles (RCF, RPM, Sedimentation coefficient etc); Technique and applications; Types of centrifuge- Microcentrifuge, High speed and Ultracentrifuges; Types of Rotors: fixed angle, swinging bucket. Preparative centrifugation; Differential and density gradient centrifugation; Applications (Isolation of cell components); Analytical centrifugation; Determination of molecular weight by sedimentation velocity and sedimentation equilibrium methods.

**Unit IV: Spectroscopy Techniques:** Theory, principle and applications of UV-Visible, Raman Spectroscopy, fluorimetry, Circular Dichroism; NMR, PMR, ESR and Plasma Emission spectroscopy; Different types of Microscopic techniques and X-ray crystallography.

**Unit V: Radioactivity:** Radioactivity and stable isotopes; Rate of radioactive decay with units; Measurement-Geiger-Muller counter; Solid and Liquid scintillation counters (Basic principle, instrumentation and technique); Brief idea of radiation dosimetry; Cerenkov radiation; Autoradiography; Falling drop method; Applications of isotopes in biochemistry; Radiotracer techniques; Distribution studies; Isotope dilution technique and Metabolic studies.

### **Texts/References**

1. Freifelder D., Physical Biochemistry, Application to Biochemistry and Molecular Biology, 2nd Edition, W.H. Freeman and Company, San Fransisco, 1982.
2. Keith Wilson and John Walker, Principles and Techniques of Practical Biochemistry, 5th Edition, Cambridge University Press, 2000.
3. D. Holme and H. Peck, Analytical Biochemistry, 3rd Edition, Longman, 1998.
4. R. Scopes, Protein Purification - Principles & Practices, 3rd Edition, Springer Verlag, 1994.
5. Selected readings from Methods in Enzymology, Academic Press.

## **MBT-104**

### **Paper Fourth**

#### **Fundamentals in Biostatistics and Biomathematics (Max. marks:100)**

**Unit I:** Relation and Functions, Mathematical Modeling, Logarithms, Complex numbers, Linear and Quadratic equations, Sequence and series, Simple trigonometry, Cartesian system of rectangular coordinates, straight lines and family, Circles, permutation and combination. Binomial theorem, Binomial expansion, Exponential and Logarithmic series. Mathematical logic, Index numbers, Matrices and Determinants, Boolean Algebra, Functions, Limits and continuity, Differentiation, Application of Derivatives, Differential Equations, Simple integrations.

**Unit II:** Set theory, set operations and rules; Fundamental concepts in applied probability; Counting and Probability; Inclusion-exclusion rule; Conditional probability: Bayes' theorem; Probability and analysis of one and two way samples; discrete and continuous probability models; probability distributions (Binomial, Poisson and normal), Exploratory data analysis and statistical inference; Euler's theorem and its application, data clustering.

**Unit III:** Data collection and representation, classification, significant digits, rounding off, Error analysis Independence Descriptive statistics and Random variables; Measures of central tendency and dispersal; Expectation and variance; Measures of spread: range, percentile, standard deviation; kurtosis, skew; frequency distributions; Discrete random variables: sampling, methods of sampling, advantages; sampling variability, population and sample, Standard normal distribution, standard normal deviate.

**Unit IV:** Sampling distribution; Difference between parametric and non-parametric statistics; Confidence Interval; Errors; Sampling distributions, Hypothesis testing: null and alternative hypotheses, confidence limit, level of significance, chi-square, F distributions, type I and type II errors, P-value of the statistic; Introduction to one way and two-way analysis of variance; One-way ANOVA, Curve fitting, Regression and Correlation.

**Texts/References**

1. G. B. Thomas and R. L. Finney, Calculus and Analytic Geometry, 9th Edition, ISE Reprint, AddisonWesley, 1998.
2. E. Kreyszig, Advanced engineering mathematics, 8th Edition, John Wiley, 1999.
3. W. E. Boyce and R. DiPrima, Elementary Differential Equations, 8th Edition, John Wiley, 2005.

**MBT-105**  
**Practicals (Max. marks: 100)**  
**Based on theory subjects**

**M.Sc. BIOTECHNOLOGY SECOND SEMESTER**

**M.Sc. IInd Semester**

**MBT-201**

**Paper First**

**Molecular Biology and Genetics (Max. marks: 100)**

**Unit I:** Genome organization; Organization of bacterial and eukaryotic chromosomes; Structure of DNA; Heterochromatin and Euchromatin; DNA reassociation kinetics (Cot curve analysis); Satellite DNA; DNA melting and buoyant density; DNase I hypersensitive regions; DNA methylation and Imprinting. Replication: initiation, elongation and termination in prokaryotes and eukaryotes; Enzymes and accessory proteins; Fidelity; Replication of single stranded circular DNA; Recombination: Homologous and non-homologous.

**Unit II:** Prokaryotic Transcription; Transcription unit; Promoters- Constitutive and Inducible; Operators; Regulatory elements; Initiation; Attenuation; Termination-Rho-dependent and independent; Anti-termination; Transcriptional regulation-Positive and negative; Operon concept-lac, trp, ara, his, and gal operons; RNA polymerase I, II, III; Eukaryotic promoters and enhancers; General Transcription factors; TATA binding proteins (TBP) and TBP associated factors (TAF); Activators and repressors; Transcriptional and post-transcriptional gene silencing: breakdown of selective and specific mRNAs through interference by small non-coding RNAs (miRNAs and siRNAs).

**Unit III:** Post Transcriptional Modifications, Processing of hnRNA, tRNA, rRNA; 5'-Cap formation; 3'-end processing and polyadenylation; Splicing; RNA editing; Nuclear export of mRNA; mRNA stability; Catalytic RNA. Translation: Termination codons; Isoaccepting tRNA; Wobble hypothesis; Mechanism of initiation, elongation and termination; Co- and post-translational modifications; Transport: Translation machinery; Ribosomes; Composition and assembly; Universal genetic code; Degeneracy of codons. Aminoacylation of tRNA, tRNA-identity, aminoacyl tRNA synthetase, and translational proof-reading, translational inhibitors.

**Unit IV:** Introduction to the elements of population genetics: genetic variation, genetic drift, neutral evolution; mutation selection, balancing selection, Fishers theorem, Hardy Weinberg equilibrium, linkage disequilibrium; in-breeding depression & mating systems; population bottlenecks, migrations, Bayesian statistics; adaptive landscape, spatial variation & genetic fitness. Mutations; Gene stability and DNA repair- enzymes; Photoreactivation; Nucleotide excision repair; Mismatch correction; SOS repair; Transposition - Transposable genetic elements in prokaryotes and eukaryotes; Mechanisms of transposition; Role of transposons in mutation.

**Unit V:** Concept of gene: Allele, multiple alleles, gene interactions, pleiotropy, genomic imprinting, isodisomy; Complex inheritance-genetic and environmental variation; Heritability;

Twin studies; Behavioral traits; Analysis of quantitative and qualitative traits; penetrance and expressivity, phenocopy, linkage and crossing over; Gene mapping.

#### **Texts/References**

1. S.R. Maloy, J.E. Cronan, D. Friefelder, Microbial Genetics, 2nd Edition, Jones and Bartlett Publishers, 1994.
2. N. Trun and J. Trempy, Fundamental Bacterial Genetics, Blackwell publishing, 2004.
3. Strachan T and Read A P, Human molecular genetics, 3rd Edition Wiley Bios, 2006.
4. Mange E J and Mange A. P., Human genetics, 2nd Edition, Sinauer Associates publications, 1999.
5. Hartl L D and Jones B, Analysis of genes and genomes, 3rd Edition, Jones and Bartlett Publishers, 1994.
6. Benjamin Lewin, Gene IX, 9th Edition, Jones and Barlett Publishers, 2007.
7. J.D. Watson, N.H. Hopkins, J.W Roberts, J. A. Seitz & A.M. Weiner; Molecular Biology of the Gene, 6th Edition, Benjamin Cummings Publishing Company Inc, 2007.
8. Alberts et al; Molecular Biology of the Cell, 4th edition, Garland, 2002.

### **MBT -202**

#### **Paper Second**

#### **Microbiology (Max. marks: 100)**

**Unit I:** Microbial Diversity and Systematics- Classical and modern methods and concepts; Domain and Kingdom concepts in classification of microorganisms; Criteria for classification; Classification of Bacteria; 16S rDNA sequencing and Ribosomal Database Project.

**Unit II:** Microbial Growth and Physiology: Ultrastructure of Archaea (Methanococcus); Eubacteria (E.coli); Unicellular Eukaryotes (Yeast); Concept of species and strains; Microbial growth: Batch, fed-batch, continuous kinetics, synchronous growth, yield constants, methods of growth estimation, stringent response, death of a bacterial cell. Microbial physiology: Physiological adaptation and life style of Prokaryotes; Unicellular Eukaryotes and the Extremophiles (with classical example from each group).

**Unit III:** Microbial Interactions and Infection; Host–Pathogen interactions; Microbes infecting humans, veterinary animals and plants; Pathogenicity islands and their role in bacterial virulence.

**Unit IV:** Microbes and Environment: Role of microorganisms in natural system and artificial system; Influence of Microbes on the Earth’s Environment and Inhabitants; Ecological impacts of microbes; Symbiosis (Nitrogen fixation and ruminant symbiosis); Microbes and Nutrient cycles; Microbial communication system; Quorum sensing; Microbial fuel cells; Prebiotics and Probiotics.



**Unit V:** General Virology; Morphology and Ultrastructure of viruses (Bacterial, Plant, Animal, Tumor viruses), Satellite viruses; Properties of viruses; Virus like particles-Viroids, prions, Cultivation of viruses in embryonated eggs; General overview of bacteriophages, plant and animal viruses (TMV, CsMV, HIV, Rota, Toga, Rhabdo). Economic loss due to important viruses; Infectivity assays-Sap transmission; insect vector transmission; Agrobacterium mediated; Gene Silencing-Viral suppression.

### **Texts/References**

1. Pelczar MJ Jr., Chan ECS and Kreig NR., Microbiology, 5th Edition, Tata McGraw Hill, 1993.
2. Maloy SR, Cronan JE Jr., and Freifelder D, Microbial Genetics, Jones Bartlett Publishers, Sudbury, Massachusetts, 2006.
3. Cruieger and A Cruieger, (English Ed., TDW Brock); Biotechnology: A textbook of Industrial Microbiology, Sinaeur Associates, 1990.
4. G Reed, Prescott and Dunn's, Industrial Microbiology, 4th Edition, CBS Publishers, 1987.
5. M.T. Madigan and J.M. Martinko, Biology of Microorganisms, 11th Edition, Pearson Prentice Hall, USA, 2006.

## **MBT-203**

### **Paper Third**

#### **Physiology and Metabolism (Max. marks: 100)**

**Unit I:** Bioenergetics-basic principles; Equilibria and concept of free energy; Coupled processes; Logic and integration of central metabolism; entry/ exit of various biomolecules from central pathways; Principles of metabolic regulation; Regulatory steps.

**Unit II:** Photorespiration; Sensory photobiology - Mechanisms of action of phytochromes, cryptochromes and phototropins; stomatal movement; photoperiodism and biological clocks; Photosynthesis: Light harvesting complexes; mechanisms of electron transport; photoprotective mechanisms; CO<sub>2</sub> fixation-C<sub>3</sub>, C<sub>4</sub> and CAM pathways.

**Unit III:** Solute transport and photoassimilate translocation; transpiration; Stress physiology – Responses of plants to biotic (pathogen and insects) and abiotic (water, temperature and salt) stresses.

**Unit IV:** Metabolism of carbohydrates; Glycolysis, Kreb's cycle, oxidative phosphorylation, gluconeogenesis; Glycogenesis; Pentose phosphate Pathway and its regulation. Lipids

Metabolism: Beta oxidation and Omega oxidation of fatty acids (odd and even), phospholipids and sphingolipids metabolism, fatty acid and cholesterol biosynthesis and its regulation. Metabolism of amino acids: Amino acid degradation, biosynthesis and inborn error in amino acid metabolism. Metabolism and regulation of purines, pyrimidines, Nitrogen Fixation and nitrogenous compounds and their roles.

**Unit V:** Plasma function, Cardiovascular System: Cellular respiration: and respiratory quotient; Digestive system - Digestion, absorption, energy balance, BMR; Respiratory system; transport of gases, exchange of gases, waste elimination, neural and chemical regulation of respiration. Nervous system - Neurons, action potential, Excretory system - kidney, urine formation, urine concentration, waste elimination, micturition, regulation of water balance, blood volume, blood pressure, electrolyte balance, acid-base balance; Thermoregulation - Comfort zone, body temperature – physical, chemical, neural regulation, acclimatization; Endocrinology - Endocrine glands, basic mechanism of hormone action.

#### **Texts/References**

1. Stryer, L. (2015). Biochemistry. (8th ed.) New York: Freeman.
2. Lehninger, A. L. (2012). Principles of Biochemistry (6th ed.). New York, NY: Worth.
3. Voet, D., & Voet, J. G. (2016). Biochemistry (5th ed.). Hoboken, NJ: J. Wiley & Sons.
4. Dobson, C. M. (2003). Protein Folding and Misfolding. Nature, 426(6968), 884-890. doi:10.1038/nature02261.
5. Richards, F. M. (1991). The Protein Folding Problem. Scientific American, 264(1), 54-63. doi:10.1038/scientificamerican0191-54.
6. Buchanan, B. B., Gruissem, W., & Jones, R. L. (2015). Biochemistry & Molecular Biology of Plants. Chichester, West Sussex: John Wiley & Sons.
7. Gordon, I. (2005). Reproductive Techniques in Farm Animals. Oxford: CAB International.
8. Levine, M. M. (2004). New Generation Vaccines. New York: M. Dekker.
9. Pörtner, R. (2007). Animal Cell Biotechnology: Methods and Protocols. Totowa, NJ: Humana Press.

### **MBT-204**

#### **Paper Fourth**

#### **Computational Biology and Bioinformatics (Max. marks: 100)**

**Unit I:** Basic organization of computers, Software's, Hardware's, Memory, Storage devices, Binary number system, Algorithms, Basic of programming - C; High and low level languages, Compiler, Interpreter, Assembler, HTML, TCP/IP, Cloud computing, Computer viruses, Data base concept; Database management system; Database browsing and Data retrieval; Biological Databases, Sequence, Structure, Pathway, Compound and Drug binding databases, Searching, retrieval and interpretation of database results.

**Unit II:** Sequence and structure file format, Sequence alignments and analysis, Local and Global sequence alignment, multiple sequence alignment, BLAST, Phylogenetic tree, Basics of PAM and BLOSUM matrices, ORF analysis, Theory of profiles and their use in sequence analysis; Concept of HMMS and their applications, Concept of genetic algorithm, artificial neural network and clustering.

**Unit III:** Goals of a Microarray experiment, Detecting differential gene expression; Principal component analysis; Clustering of microarray data; Application of Proteomics and genomics analysis tools, Structure determination by X-ray crystallography; NMR spectroscopy, structure visualization, PDB.

**Unit IV:** Methods for structure modelling; Homology modeling; Threading and *Ab initio* methods; structure validation and Ramachandran plot, Mutant modeling, Structure-structure comparison of macromolecules; Molecular energy minimization, Molecular dynamics simulation, Introduction to computer aided drug designing, Structure and ligand based drug designing, lead compounds and optimization, Molecular docking, Protein-ligand interaction analysis, Absorption distribution, metabolism and excretion parameters (ADMET) prediction and analysis.

**Texts/References:**

1. Wayne W. Daniel, Biostatistics : A foundation for Analysis in the Health Sciences, 8th Edition, Wiley, 2004.
2. Prem S. Mann, Introductory Statistics, 6th Edition, Wiley, 2006.
3. John A. Rice, Mathematical Statistics and Data Analysis, 3rd Edition, John A. Rice, Duxbury Press, 2006.
4. Campbell and Heyer, Discovering Genomics, Proteomics, & Bioinformatics, 2nd Edition, Benjamin Cummings, 2002.
5. Cynthia Gibas and Per Jambeck, Developing Bioinformatics Computer Skill, 1st Edition, O'Reilly Publication, 2001.

**MBT-205**  
**Practicals**  
**Based on theory subjects**

## **M.Sc. III SEMESTER BIOTECHNOLOGY**

### **MBT-301**

#### **Paper First**

#### **Cellular and Molecular Immunology (Max. marks: 100)**

**Unit I:** Immunology- Fundamental concepts and anatomy of the immune system; Components of innate and acquired immunity; Phagocytosis; Complement and Inflammatory responses; Haematopoiesis; Organs and cells of the immune system- primary and secondary lymphoid organs-Bone marrow, thymus, lymph nodes, spleen; Lymphatic system; Lymphocyte circulation; Lymphocyte homing; Mucosal and Cutaneous associated Lymphoid tissue (MALT and CALT); Mucosal Immunity. Toll-like receptors, inflammation. Antigens - haptens, antigenicity and immunogenicity.

**Unit II:** Humoral and Cell-Mediated Immune responses, primary and secondary immune modulation, Immunoglobulins: Basic structure, Classes and Subclasses of immunoglobulins, ADCC; antigenic determinants; B and T cell epitopes; B and T cell receptors; Immune responses generated by B and T lymphocytes; activation and differentiation of B and T cells, Memory B cell maturation, activation and differentiation; Cell-mediated effector functions; Functional T Cell Subsets; Cell-mediated immune responses, Cytokines-properties, receptors and therapeutic uses. Structure and function of antibody molecules; Multigene organization of immunoglobulin genes; Immunoglobulin superfamily; Generation of antibody diversity.

**Unit III:** Major Histocompatibility Complex - MHC genes, MHC and immune responsiveness and disease susceptibility, HLA typing; MHC molecules, antigen processing and presentation, endogenous antigens, exogenous antigens, non-peptide bacterial antigens and super-antigens.

**Unit IV:** Antigen-antibody interactions- Kinetics of immune response; Precipitation, agglutination and complement mediated immune reactions; Advanced immunological techniques; RIA, ELISA, Western blotting, ELISPOT assay, immunofluorescence, flow cytometry and immunoelectron microscopy; Surface plasmon resonance, Biosenor assays for assessing ligand-receptor interaction, CMI techniques- lymphoproliferation assay, Mixed lymphocyte reaction, Cell Cytotoxicity assays, Apoptosis, Microarrays.

**Unit V:** Clinical Immunology: Immunity to Infection Hypersensitivity – Type I-IV; Autoimmunity; Types of autoimmune diseases; Mechanism and role of CD4+ T cells; MHC and TCR in autoimmunity; Treatment of autoimmune diseases; Transplantation immunology– Immunological basis of graft rejection; congenital and acquired immunodeficiencies. Cancer: Tumor immunology; Oncogenes, Tumor Suppressor Genes; Immune response to tumors and tumor evasion of the immune system.

## **Texts/References**

1. Kindt, T. J., Goldsby, R. A., Osborne, B. A., & Kuby, J. (2006). Kuby Immunology. New York: W.H. Freeman.
2. Brostoff J, Seaddin JK, Male D, Roitt IM., Clinical Immunology, 6th Edition, Gower Medical Publishing, 2002.
3. Janeway et al., Immunobiology, 4th Edition, Current Biology publications., 1999.
4. Paul, Fundamental of Immunology, 4th edition, Lippencott Raven, 1999.
5. Murphy, K., Travers, P., Walport, M., & Janeway, C. (2012). Janeway's Immunobiology. New York: Garland Science.
6. Goding, Monoclonal antibodies, Academic Press. 1985.

## **MBT-302**

### **Paper Second**

### **Principles of Genetic Engineering (Max. marks: 100)**

**Unit I:** Basics Concepts- Restriction Enzymes; DNA ligase, Klenow enzyme, T4 DNA polymerase, Polynucleotide kinase, Alkaline phosphatase; Cohesive and blunt end ligation; Linkers; Adaptors; Homopolymeric tailing; Labeling of DNA: Nick translation, Random priming, Radioactive and non-radioactive probes, Hybridization techniques: Northern, Southern and Colony hybridization, Fluorescence in situ hybridization; DNA-Protein Interactions- Electromobility shift assay; DNaseI footprinting; Methyl interference assay.

**Unit II:** Cloning Vectors -Plasmids; Bacteriophages; M13 mp vectors; PUC19 and Bluescript vectors, Phagemids; Lambda vectors; Insertion and Replacement vectors; Cosmids; Artificial chromosome vectors (YACs; BACs); Animal Virus derived vectors-SV-40; vaccinia/baculo and retroviral vectors; Expression vectors; pMal; GST; pET-based vectors; Protein purification; His-tag; GST-tag; MBP-tag, FLAG etc.; Intein-based vectors; Inclusion bodies; Methodologies to reduce formation of inclusion bodies; Baculovirus and pichia vectors system, Plant based vectors, Ti and Ri as vectors, Yeast vectors, Shuttle vectors.

**Unit III:** Cloning Methodologies- Insertion of Foreign DNA into Host Cells; Transformation; Construction of libraries; Isolation of mRNA and total RNA; cDNA and genomic libraries; cDNA and genomic cloning; Expression cloning; Jumping and hopping libraries; Southwestern and Far-western cloning; Protein-protein interactive cloning and Yeast two hybrid system; Phage display; Principles in maximizing gene expression.

**Unit IV:** PCR and Its Applications- Primer design; Fidelity of thermostable enzymes; DNA polymerases; Types of PCR – multiplex, nested, reverse transcriptase, real time PCR, touchdown PCR, hot start PCR, colony PCR, cloning of PCR products; Tvectors; Proof reading enzymes; PCR in gene recombination; Deletion; addition; Overlap extension; and SOEing; Site specific mutagenesis; PCR in molecular diagnostics; Viral and bacterial detection; PCR based mutagenesis, Mutation detection: SSCP, DGGE, RFLP, Oligo Ligation Assay (OLA), MCC (Mismatch Chemical Cleavage, ASA (Allele-Specific Amplification), PTT (Protein Truncation Test).

**Unit V:** Sequencing methods; Enzymatic DNA sequencing; Chemical sequencing of DNA; Automated DNA sequencing; Pyrosequencing; RNA sequencing; Chemical Synthesis of oligonucleotides; Genome editing tools and techniques; Introduction of DNA into mammalian cells; Transfection techniques; Gene silencing techniques; Introduction to siRNA; siRNA technology; Micro RNA; Construction of siRNA vectors; Principle and application of gene silencing; Gene knockouts; Differential gene expression and protein array.

### **Text/References**

1. S.B. Primrose, R.M. Twyman and R.W.Old; Principles of Gene Manipulation. 6th Edition, S.B.University Press, 2001.
2. J. Sambrook and D.W. Russel; Molecular Cloning: A Laboratory Manual, Vols 1-3, CSHL, 2001.
3. Brown TA, Genomes, 3rd ed. Garland Science 2006
4. Selected papers from scientific journals.
5. Technical Literature from Stratagene, Promega, Novagen, New England Biolab etc.

## **MBT303**

### **Paper Third**

#### **Plant Biotechnology and tissue culture (Max. marks: 100)**

**Unit I:** Plant tissue culture: historical perspective; Culture Media: Preparation and Sterilization; nutrients and plant hormones; sterilization techniques; Cell and Tissue culture techniques; Introduction to different types of culture; Subculturing; Cell Induction and Maintenance. totipotency; organogenesis; Somatic embryogenesis; establishment of cultures – callus culture, cell suspension culture.

**Unit II:** Tissue culture techniques - micropropagation; somaclonal variation; androgenesis and its applications in genetics and plant breeding; germplasm conservation and cryopreservation; synthetic seed production; protoplast culture and somatic hybridization - protoplast isolation; culture and usage; somatic hybridization - methods and applications; cybrids and somatic cell genetics; plant cell cultures for secondary metabolite production and uses.

**Unit III:** Genetic engineering: Agrobacterium-plant interaction; virulence; Ti and Ri plasmids; opines and their significance; T-DNA transfer; disarmed Ti plasmid; Genetic transformation - Agrobacterium-mediated gene delivery; cointegrate and binary vectors and their utility; direct gene transfer - PEG-mediated, electroporation, particle bombardment and alternative methods; screenable and selectable markers;

**Unit IV:** Characterization of transgenics; chloroplast transformation; marker-free methodologies; advanced methodologies - cisgenesis, intragenesis and genome editing; Secondary metabolites, production and uses

**Unit V:** Overview of plant genomics – definition, complexity and classification; need for genomics level analysis; methods of analyzing genome at various levels – DNA, RNA, protein, metabolites and phenotype; genome projects and bioinformatics resources for genome research –

databases; overview of forward and reverse genetics for assigning function for genes. Molecular pharming - concept of plants as biofactories, production of industrial enzymes and pharmaceutically important compounds; strategies for Introducing genes of biotic and abiotic stress resistance in plants.

### **Text/Reference Books:**

1. Chawla, H. S. (2000). Introduction to Plant Biotechnology. Enfield, NH: Science.
2. Razdan, M. K. (2003). Introduction to Plant Tissue Culture. Enfield, NH: Science.
3. Slater, A., Scott, N. W., & Fowler, M. R. (2008). Plant Biotechnology: an Introduction to Genetic Engineering. Oxford: Oxford University Press.
4. Buchanan, B. B., Gruissem, W., & Jones, R. L. (2015). Biochemistry & Molecular Biology of Plants. Chichester, West Sussex: John Wiley & Sons.
5. Umesha, S. (2013). Plant Biotechnology. The Energy And Resources.
6. Glick, B. R., & Pasternak, J. J. (2010). Molecular Biotechnology: Principles and Applications of Recombinant DNA. Washington, D.C.: ASM Press.
7. Brown, T. A. (2006). Gene Cloning and DNA Analysis: an Introduction. Oxford: Blackwell Pub.
8. Primrose, S. B., & Twyman, R. M. (2006). Principles of Gene Manipulation and Genomics. Malden, MA: Blackwell Pub.
9. Slater, A., Scott, N. W., & Fowler, M. R. (2003). Plant Biotechnology: The Genetic Manipulation of Plants. Oxford: Oxford University Press.

## **MBT-304**

### **Paper Fourth**

#### **Enzymology and Enzyme Technology (Max. marks:100)**

**Unit I:** Introduction to Enzymes: An introduction to proteins and enzymes; Enzymes- history; General structure, Purification strategies; Their nomenclature and classification; Measures of Enzyme activity and units (Katal and IU). Proteinaceous and non protein enzymes as Ribozymes and DNAzymes. Metalloenzymes and metal activated enzymes. General properties of enzymes and enzyme assays; Introduction to Coenzymes and Cofactors- Prosthetic groups, their involvement in different metabolic pathways. Classification of coenzymes. Isozymes, Abzymes, Synzyme; Inducible and constitutive enzymes.

**Unit II:** Enzyme Catalysis and Inhibition: Various models for enzyme and substrate interactions: Lock and key, Induced fit and Transition state Hypothesis; Mechanism of enzyme catalysis- Acid-base catalysis, covalent catalysis, Metal ion catalysis, Proximity, orientation effects etc. Concept of active site; Mechanism of enzyme actions of Serine proteases-Chymotrypsin, Lysozyme, Carboxypeptidase A and Ribonuclease., Proenzymes (Zymogens). Reversible Inhibition- Competitive, Non Competitive, Uncompetitive, Mixed, Substrate, Allosteric and Product Inhibition. Irreversible Inhibition- Suicide inhibition. Mechanism of enzyme action; Examples and Mechanism of various Inhibitions like Penicillin, Iodoacetamide and DIPF.

**Unit III:** Enzyme Kinetics: Effect of enzyme concentration, pH and temperature on kinetics of enzyme reactions, enzyme inhibition; Kinetics of a single-substrate enzyme catalysed reaction, Michealis-Menten Equation,  $K_m$ ,  $V_{max}$ , L.B Plot, Briggs Haldane steady state assumption; Haldane relationship; Turnover number,  $K_{cat}$ . Kinetics of Enzyme Inhibition. Kinetics Allosteric enzymes.

**Unit IV:** Enzyme Regulation: Feedback Regulation, Allosteric Regulation, Reversible Covalent Modification and Proteolytic Activation. Subcellular localization and organisation of enzymes in the cell. compartmentation of metabolic pathways, enzymes in membranes, concentrations. Mechanisms of enzyme degradation, lysosomal and nonlysosomal pathways, examples.

**Unit V:** Industrial and Clinical uses of Enzymes: Industrial Enzymes- Thermophilic enzymes, amylases, lipases, proteolytic enzymes; Uses of enzymes in various industries as in food, meat and leather industry; **Clinical enzymes-** Role and importance of Cytochrome P450 family enzymes; Enzymes as thrombolytic agents, Anti-inflammatory agents; Designer enzymes; Drug Discovery- Properties of Enzymes (Case study of DHFR).

#### **Texts/References**

1. V.Voet and J.G.Voet, Biochemistry, 3rd edition, John Wiley, New York, 2004.
2. A.L. Lehninger, Principles of Biochemistry, 4th edition, W.H Freeman and Company, 2004.
3. L. Stryer, Biochemistry, 5th edition, W.H. Freeman and Company, 2002.

**MBT- 305**  
**Practicals**  
**Based on theory subjects**



## M.Sc. IV SEMESTER BIOTECHNOLOGY

### MBT-401

#### Paper First

#### **Animal Cell Culture, Medical and Microbial Biotechnology (Max. marks: 100)**

**Unit I:** Animal cell culture: brief history of animal cell culture; cell culture media and reagents; culture of mammalian cells, primary culture, secondary culture, continuous cell lines, suspension cultures; application of animal cell culture for virus isolation and in vitro testing of drugs, testing of toxicity of environmental pollutants in cell culture, application of cell culture technology in production of human pharmaceutical proteins. Expression of cloned gene in animal cell; Need to express; Transgenic animals (transgenic mice; gene knock outs), Disease model; detection of meat adulteration using DNA based methods.

**Unit II:** Vaccine technology: Immunity and vaccine; Herd Immunity; Rationale vaccine design based on clinical requirements: Active immunization, Attenuated; Inactivated; Subunit vaccines; Recombinant and protein based vaccines, plant-based vaccines and reverse vaccinology; Peptide vaccines, conjugate vaccines; Passive Immunization; Monoclonal Antibody production: Hybridoma and Phage display; Applications of antibodies; ScFv; Abzymes; antibody engineering; Chimeric antibody.

**Unit III:** Important therapeutic proteins: Functions, Uses and Production of- Insulin, Growth Hormone, Alpha-1-antitrypsin, Factor VIII, Tissue-Plasminogen Activator; FGF, NGF, EGF, Erythropoietin.

**Unit IV:** Biotechnological methods of disease diagnosis and treatment- Microbiological; Immunological; Serological; Molecular diagnostics-PCR, NAAT, Microarray technology; cDNA and intragenic arrays.

Basic concept of Pharmacogenomics; Companion diagnostics; Gene based chips and arrays; Antibiotics-classes, function and production; Interferons: Types, Uses and Production; Molecular markers - hybridization and PCR based markers RFLP, RAPD, STS, SSR, AFLP, SNP markers; introduction to mapping of genes/QTLs; marker-assisted selection; Forensic medicine: DNA fingerprinting-principles and applications; DNA profiling.

**Unit V:** In vitro fertilization and Embryo Transfer; Stem Cell therapy; Gene therapy; Somatic and germ-line therapy- in vivo and ex-vivo; Suicide gene therapy; Gene replacement; Gene targeting; Transgenics; Production of Artificial tissues and organs; Antibiotic production and applications.

#### **Texts/References**

1. F.C. Hay, O.M.R. Westwood, Practical Immunology, 4th Edition-, Blackwell Publishing, 2002
2. S. Hockfield, S. Carlson, C. Evans, P. Levitt, J. Pintar, L. Silberstein, Selected Methods for Antibody and Nucleic Acid probes, Volume1, Cold Spring Harbor Laboratory Press,1993.
3. Ed Harlow, David Lane, Antibodies Laboratory Manual, Cold Spring Harbor, Laboratory Press, 1988.
4. Gupta V et al (2016) Basics and Applied aspects of Biotechnology, Springer International.
5. Gordon, I. (2005). Reproductive Techniques in Farm Animals. Oxford: CAB International.

6. Levine, M. M. (2004). *New Generation Vaccines*. New York: M. Dekker.
7. Pörtner, R. (2007). *Animal Cell Biotechnology: Methods and Protocols*. Totowa, NJ: Humana Press.

**MBT-402**  
**Paper Second**  
**Genomics, Proteomics,**  
**Intellectual Property rights, Product Regulation and Biosafety (Max. marks:100)**

**Unit I:** Introduction: Structural organization of genome in Prokaryotes and Eukaryotes; Organelle DNA-mitochondrial, chloroplast; DNA sequencing-principles and translation to large scale projects; Recognition of coding and non-coding sequences and gene annotation; Linkage and Pedigree analysis-physical and genetic mapping. Genome sequencing projects, Accessing and retrieving genome project information from web; Comparative genomics, Identification and classification using molecular markers-16S rRNA typing/sequencing, ESTs and SNPs.

**Unit II:** Proteomics: Protein analysis (includes measurement of concentration, amino-acid composition, N-terminal sequencing); 2-D electrophoresis of proteins; Microscale solution isoelectric focusing; Peptide fingerprinting; LC/MS-MS for identification of proteins and modified proteins; MALDI-TOF; SAGE and Differential display proteomics, Protein-protein interactions, Yeast two hybrid system.

**Unit III:** Pharmacogenetics: High throughput screening in genome for drug discovery-identification of gene targets, Pharmacogenetics and drug development; Functional genomics and proteomics; Analysis of microarray data; Protein and peptide microarray-based technology; PCR-directed protein in situ arrays; Structural proteomics.

**Unit IV:** Introduction to Intellectual Property; Types of IP: Patents (Basics of Patents; Types of patents; Indian Patent Act 1970; Recent Amendments; Filing of a patent application; Precautions before patenting-disclosure/non-disclosure; Patent filing and Infringement; Trademarks, Copyright and Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications, Protection of New GMOs; International framework for the protection of IP as a factor in RandD; Entrepreneurship-Few Case Studies; Introduction to GATT, WTO, WIPO and TRIPS.

**Unit V:** Biosafety Introduction; Historical Background; Introduction to Biological Safety Cabinets; Primary Containment for Biohazards; Biosafety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals; Biosafety guidelines - Government of India; Definition of GMOs and LMOs; Roles of Institutional Biosafety Committee, RCGM, GEAC etc. for GMO applications in food and agriculture; Environmental release of GMOs; Risk Analysis; Risk Assessment; Risk management and communication; Overview of National Regulations and relevant International Agreements including Cartagena Protocol.

**Texts/References**

1. Voet D, Voet JG & Pratt CW, *Fundamentals of Biochemistry*, 2nd Edition. Wiley 2006

2. Brown TA, Genomes, 3rd Edition. Garland Science 2006
3. Campbell AM & Heyer LJ, Discovering Genomics, Proteomics and Bioinformatics, 2nd Edition. Benjamin Cummings 2007
4. Primrose S & Twyman R, Principles of Gene Manipulation and Genomics, 7th Edition, Blackwell, 2006.
5. Glick BR & Pasternak JJ, Molecular Biotechnology, 3rd Edition, ASM Press, 1998.

**MBT-403A**  
**Paper Third**  
**Industrial Biotechnology (Max. marks:100)**

**Unit I:** Basic principles in bioprocess technology; Isolation, screening and maintenance of industrially important microbes; Microbial growth and death kinetics; Media Formulation; Sterilization; Bioreactor designs; Types of fermentation and fermenters

**Unit II:** Concepts of basic modes of fermentation - Batch, fed batch and continuous. Conventional fermentation v/s biotransformation; Solid substrate, surface and submerged fermentation; Fermentation economics; Fermentation media; Fermenter design- mechanically agitated; Pneumatic and hydrodynamic fermenters; Bioprocess control and monitoring variables such as temperature, agitation, pressure, pH Microbial processes-production, optimization, screening, strain improvement,

**Unit III:** Factors affecting down stream processing and recovery; Representative examples of ethanol, organic acids, antibiotics etc. Primary and secondary metabolites; Extracellular enzymes; Biotechnologically important intracellular products; exopolymers.

**Unit IV:** Enzyme Technology-production, recovery, stability and formulation of bacterial and fungal enzymes-amylase, protease, penicillin acylase, glucose isomerase; Immobilised Enzyme and Cell based bio transformations steroids, antibiotics, alkaloids, enzyme/cell electrodes. Enzymic bioconversions e.g. starch and sugar conversion processes; High-Fructose Corn Syrup; Interesterified fat; Hydrolyzed protein etc. and their downstream processing; Biosensors.

**Texts/References:**

1. Shuler, M. L., & Kargi, F. (2002). Bioprocess Engineering: Basic Concepts. Upper Saddle River, NJ: Prentice Hall.
2. Stanbury, P. F., & Whitaker, A. (2010). Principles of Fermentation Technology. Oxford: Pergamon Press.
3. Blanch, H. W., & Clark, D. S. (1997). Biochemical Engineering. New York: M. Dekker.
4. Bailey, J. E., & Ollis, D. F. (1986). Biochemical Engineering Fundamentals. New York: McGraw-Hill.
5. El-Mansi, M., & Bryce, C. F. (2007). Fermentation Microbiology and Biotechnology. Boca Raton: CRC/Taylor & Francis.

**MBT-403B**  
**Paper Third**  
**Environmental Biotechnology (Max. marks: 100)**

**Unit I:** Waste water management: domestic, industrial, solid and hazardous wastes; strain improvement; Water usage and recycling; Effluent treatment and disposal.

**Unit II:** Introduction to environment; pollution and its control; pollution indicators; Biodiversity and its conservation; Brief overview of geochemical cycles and role of microorganisms.

**Unit III:** Bioremediation: Fundamentals, methods and strategies of application (biostimulation, bioaugmentation) – examples, bioremediation of metals (Cr, As, Se, Hg), radionuclides (U, Te), organic pollutants (PAHs, PCBs, Pesticides, TNT etc.), technological aspects of bioremediation (in situ, ex situ). Application of bacteria and fungi in bioremediation: White rot fungi vs specialized degrading bacteria: examples, uses and advantages vs disadvantages; Phytoremediation: Fundamentals and description of major methods of application (phytoaccumulation, phytovolatilization, rhizofiltration phytostabilization).

**Unit IV:** Bioinsecticides: *Bacillus thuringiensis*, Baculoviruses. Biofungicides: Description of mode of actions and mechanisms (e.g. *Trichoderma*, *Pseudomonas fluorescens*); Biofertilizers: Symbiotic systems between plants – microorganisms (nitrogen fixing symbiosis, mycorrhiza fungi symbiosis), Plant growth promoting rhizobacteria (PGPR) – uses, practical aspects and problems in application.

**Unit V:** Biofuels: production and benefits of biogas; bioethanol; biodiesel; biohydrogen ; Microbiologically enhanced oil recovery (MEOR); Bioleaching of metals; Production of bioplastics; Production of biosurfactants: bioemulsifiers; Paper production: use of xylanases and white rot fungi.

**Texts/References:**

1. G. M. Evans and J. C. Furlong (2003), Environmental Biotechnology: Theory and Applications, Wiley Publishers.
2. B. Ritmann and P. L. McCarty, (2000), Environmental Biotechnology: Principle & Applications, 2nd Ed., McGraw Hill Science.
3. Scragg A., (2005) Environmental Biotechnology. Pearson Education Limited.
4. J. S. Devinny, M. A. Deshusses and T. S. Webster, (1998), Biofiltration for Air Pollution Control, CRC Press.
5. H. J. Rehm and G. Reed, (2001), Biotechnology – A Multi-volume Comprehensive Treatise, Vol. 11, 2nd Ed., VCH Publishers Inc.
6. H. S. Peavy, D. R. Rowe and G. Tchobanoglous, (2013), Environmental Engineering, McGraw-Hill Inc.

**MBT-403C**  
**Paper Third**  
**Drug Discovery and Development (Max. marks: 100)**

**Unit I:** Identification of target or drug leads associated with a particular disease by a number of different techniques including combinations of molecular modeling, combinatorial libraries and high-throughput screening (HTS); Conceptualizing the automation of the HTS process and the importance of bioinformatics and data processing in identification of lead compounds; Rational drug design, based on understanding the three-dimensional structures and physicochemical properties of drugs and receptors; receptor-based and ligand-based design and docking methods, in silico screening of libraries, semi-empirical and ab-initio methods, QSAR methods, molecular diversity, design of combinatorial libraries of drug-like molecules, macromolecular and chemical databases.

**Unit II:** Identification of relevant groups on a molecule that interact with a receptor and are responsible for biological activity; Understanding structure activity relationship; Structure modification to increase potency and therapeutic index; Concept of quantitative drug design using Quantitative structure–activity relationship models (QSAR models) based on the fact that the biological properties of a compound are a function of its physicochemical parameters such as solubility, lipophilicity, electronic effects, ionization, stereochemistry, etc.; Bioanalytical assay development in support of in vitro and in vivo studies (LC/MS/MS, GC/MS and ELISA).

**Unit III:** Principles of drug absorption, drug metabolism and distribution - intestinal absorption, metabolic stability, drug-drug interactions, plasma protein binding assays, metabolite profile studies, Principles of toxicology, Experimental design for preclinical and clinical PK/PD/TK studies, Selection of animal model.

**Unit IV:** Requirements of GMP implementation, Documentation of GMP practices, CoA, Regulatory certification of GMP, Quality control and Quality assurance, concept and philosophy of TQM, ICH and ISO 9000; ICH guidelines for Manufacturing, Understanding Impurity Qualification Data, Stability Studies.

**Unit V:** Objectives of Phase I, II, III and IV clinical studies, Clinical study design, enrollment, sites and documentation, Clinical safety studies: Adverse events and adverse drug reactions, Clinical PK, pharmacology, drug-drug interaction studies, Statistical analysis and documentation.

Global Regulatory Affairs and different steps involved, Regulatory Objectives, Regulatory Agencies; FDA guidelines on IND and NDA submissions.

**Textbooks and References:**

1. Krogsgaard-Larsen et al. Textbook of Drug Design and Discovery. 4th Edition. CRC Press.
2. Kuhse, H. (2010). Bioethics: an Anthology. Malden, MA: Blackwell.
3. Nally, J. D. (2006) GMP for Pharmaceuticals. 6th edition. CRC Press
4. Brody, T. (2016) Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines. Academic Press.

**MBT-403D**  
**Paper Third**  
**Nanobiotechnology (Max. marks: 100)**

**Unit I:** Introduction to Nanobiotechnology; Concepts, historical perspective; Different formats of nanomaterials and applications with example for specific cases; Cellular Nanostructures; Nanopores; Biomolecular motors; Bio-inspired Nanostructures, Synthesis and characterization of different nanomaterials. Thin films; Colloidal nanostructures; Self Assembly, Nanovesicles; Nanospheres; Nanocapsules and their characterisation.

**Unit II:** Nanoparticles for drug delivery, concepts, optimization of nanoparticle properties for suitability of administration through various routes of delivery, advantages, strategies for cellular internalization and long circulation, strategies for enhanced permeation through various anatomical barriers.

Nanoparticles for diagnostics and imaging (theranostics); concepts of smart stimuli responsive nanoparticles, implications in cancer therapy, nanodevices for biosensor development.

**Unit III:** Nanomaterials for catalysis, development and characterization of nanobiocatalysts, application of nanoscaffolds in synthesis, applications of nanobiocatalysis in the production of drugs and drug intermediates.

**Unit IV:** Introduction to Safety of nanomaterials, Basics of nanotoxicity, Models and assays for Nanotoxicity assessment; Fate of nanomaterials in different stratas of environment; Ecotoxicity models and assays; Life Cycle Assessment, containment.

**Textbooks and References:**

1. GeroDecher, Joseph B. Schlenoff, (2003); Multilayer Thin Films: Sequential Assembly of Nanocomposite Materials, Wiley-VCH Verlag GmbH & Co. KGaA
2. David S. Goodsell, (2004); Bionanotechnology: Lessons from Nature; Wiley-Liss
3. Neelina H. Malsch (2005), Biomedical Nanotechnology, CRC Press
4. Greg T. Hermanson, (2013); Bioconjugate Techniques, (3rd Edition); Elsevier
5. Recent review papers in the area of Nanomedicine.

**MBT-404**  
**Project Viva (Max. marks: 200)**  
**Based on report and presentation as per the ordinance**