KAMARAJ
COLLEGE OF ENGINEERING & TECHNOLOGY

(An Autonomous Institution - AFFILIATED TO ANNA UNIVERSITY, CHENNAI)

S.P.G.Chidambara Nadar - C.Nagammal Campus

S.P.G.C.Nagar, K.Vellakulam - 625 701, (Near Virudhunagar), Madurai District.

DEPARTMENT OF BIOTECHNOLOGY

M.TECH BIOTECHNOLOGY

R – 2020 AUTONOMOUS CURRICULUM & SYLLABUS

CHOICE BASED CREDIT SYSTEM

VISION:

To make the Department of Biotechnology, unique of its kind in the field of research and development activities pertaining to the field of biotechnology in this part of the world.

MISSION:

To impart highly innovative and technical knowledge in the field of biotechnology to the urban and rural student folks through “Total Quality Education”.

PROGRAM OUTCOMES:

PO1: An ability to independently carry out research/investigation and development work to solve practical problems

PO2: An ability to write and present a substantial technical report/document.

PO3: Students should be able to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program

SEMESTER I

S.NO	CODE	COURSE TITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIOD	CREDITS
				L	T	P		
THEORY								
1	MA1105	Applied Statistics for Biotechnologists	FC	3	1	0	4	4
2	MB1101	Advances in Bioprocess Technology	PC	3	0	0	3	3
3	MB1102	Computational Biology	PC	3	0	0	3	3
4	MB1103	Immunotechnology	PC	3	0	0	3	3
5		Professional Elective I	PE	3	0	0	3	3
6		Professional Elective II	PE	3	0	0	3	3
7		Professional Elective III	PE	3	0	0	3	3
PRACTICALS								
8	MB1111	Advanced Biochemistry and Microbiology laboratory	PC	0	0	6	6	3
TOTAL				**21**	**1**	**6**	**28**	**25**

SEMESTER II

S.NO	CODE	COURSE TITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIOD	CREDITS
				L	T	P		
THEORY								
1	MB1201	Advanced Genetic Engineering	PC	3	0	0	3	3
2	MB1202	Biosafety and Bioethics	PC	3	0	0	3	3
3	MB1203	Bioseparation Technology	PC	3	0	0	3	3
4		Professional Elective IV	PE	3	0	0	3	3
5		Professional Elective V	PE	3	0	0	3	3
6		Open Elective	OE	3	0	0	3	3
7		Online course	OL	(NPTEL/SWAYAM)				3
PRACTICALS								
8	MB1211	Immunotechnology Laboratory	PC	0	0	6	6	3
TOTAL				**18**	**0**	**6**	**24**	**24**

SEMESTER III

S.NO	CODE	COURSE TITLE	CATEGORY	PERIODS PER WEEK			TOTAL CONTACT PERIOD	CREDITS
				L	T	P		
PRACTICALS								
1	MB1311	Advanced Genetic Engineering Laboratory	PC	0	0	6	6	3
2	MB1312	Integrated Bioprocess Laboratory	PC	0	0	6	6	3
3	MB1321	Project Phase –I	EEC	0	0	12	12	6
TOTAL				**0**	**0**	**24**	**24**	**12**

SEMESTER IV

S.NO	CODE	COURSE TITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIOD	CREDITS
				L	T	P		
PRACTICALS								
1	MB1421	Project Phase – II	EEC	0	0	24	24	12
TOTAL				**0**	**0**	**24**	**24**	**12**

TOTAL NO OF CREDITS: 73

SEMESTER I, PROFESSIONAL ELECTIVES- I

S.No	COURSE CODE	COURSE TITLE	CATEGORY	CONTACT PERIODS	L	T	P	CREDITS
1	MB1131	Metabolic Process and Engineering (For Biotechnology Stream)	PE	3	3	0	0	3
2	MB1132	Molecular Concepts in Biotechnology (For Engineering Stream)	PE	3	3	0	0	3
3	MB1133	Principles of Chemical Engineering (For Science Stream)	PE	3	3	0	0	3

SEMESTER I - PROFESSIONAL ELECTIVES - II

S. No.	COURSE CODE	COURSE TITLE	CATE GORY	TOTAL CONTACT PERIODS	L	T	P	CREDITS
1	MB1134	Biomedical Devices	PE	3	3	0	0	3
2	MB1135	Bioprocess Modeling and Simulation	PE	3	3	0	0	3
3	MB1136	Environmental Biotechnology	PE	3	3	0	0	3
4	MB1137	Enzyme Engineering and Technology	PE	3	3	0	0	3
5	MB1138	Nanobiotechnology	PE	3	3	0	0	3
6	MB1139	Tissue Engineering	PE	3	3	0	0	3

SEMESTER I - PROFESSIONAL ELECTIVES – III

S. No.	COURSE CODE	COURSE TITLE	CATEGORY	TOTAL CONTACT PERIODS	L	T	P	C
1	MB1140	Advances in Animal Biotechnology	PE	3	3	0	0	3
2	MB1141	Biofuels and Platform Chemicals	PE	3	3	0	0	3
3	MB1142	Food Processing and Biotechnology	PE	3	3	0	0	3
4	MB1143	Molecular Diagnostics	PE	3	3	0	0	3
5	MB1144	Pharmaceutical Biotechnology	PE	3	3	0	0	3
6	MB1145	Research Methodology In Biotechnology	PE	3	3	0	0	3

SEMESTER II - PROFESSIONAL ELECTIVES – IV

S. No.	COURSE CODE	COURSE TITLE	CATEGORY	TOTAL CONTACT PERIODS	L	T	P	C
1	MB1231	Advanced Genomics and Proteomics	PE	3	3	0	0	3
2	MB1232	Advanced Plant Biotechnology	PE	4	2	0	2	3
3	MB1233	Advances in Molecular Pathogenesis	PE	3	3	0	0	3
4	MB1234	Bioprocess Plant Design, Economics and Practice	PE	3	3	0	0	3
5	MB1235	Computational Methods In Fluid Dynamics	PE	3	3	0	0	3
6	MB1236	Marine Biotechnology	PE	3	3	0	0	3

SEMESTER II - PROFESSIONAL ELECTIVES – V

S. No.	COURSE CODE	COURSE TITLE	CATE GORY	TOTAL CONTACT PERIODS	L	T	P	C
1	MB1237	Biogenerics and Biopharmaceuticals	PE	3	3	0	0	3
2	MB1238	Clinical Trials	PE	3	3	0	0	3
3	MB1239	GMP and validation in Bioprocess industries	PE	3	3	0	0	3
4	MB1240	Human Heredity and Genetics	PE	3	3	0	0	3
5	MB1241	Molecular Medicine and Mechanism	PE	3	3	0	0	3
6	MB1242	Principles of Intellectual Property Rights	PE	3	3	0	0	3

PROFESSSIONAL CORE COURSES (PCC)

Sl. No.	CODE NO	COURSE TITLE	L	T	P	CREDITS	SEMESTER
1	MB1101	Advances in Bioprocess Technology	3	0	0	3	I
2	MB1102	Computational Biology	3	0	0	3	I
3	MB1103	Immunotechnology	3	0	0	3	I
4	MB1111	Advanced Biochemistry and Microbiology Laboratory	0	0	6	3	I
5	MB1201	Advanced Genetic Engineering	3	0	0	3	II
6	MB1202	Biosafety and Bioethics	3	0	0	3	II
7	MB1203	Bioseparation Technology	3	0	0	3	II
8	MB1211	Immunotechnology Laboratory	0	0	6	3	II
9	MB1311	Advanced Genetic Engineering Laboratory	0	0	6	3	III
10	MB1312	Integrated Bioprocess Laboratory	0	0	6	3	III

PROFESSIONAL ELECTIVE COURSES (PEC)

S.No	COURSE CODE	COURSE TITLE	L	T	P	C	SEM
1	MB1131	Metabolic Process and Engineering (For Biotechnology Stream)	3	0	0	3	I
2	MB1132	Molecular Concepts in Biotechnology (For Engineering Stream)	3	0	0	3	I
3	MB1133	Principles of Chemical Engineering (For Science Stream)	3	0	0	3	I
4	MB1134	Biomedical Devices	3	0	0	3	I
5	MB1135	Bioprocess Modeling and Simulation	3	0	0	3	I
6	MB1136	Environmental Biotechnology	3	0	0	3	I
7	MB1137	Enzyme Engineering and Technology	3	0	0	3	I
8	MB1138	Nanobiotechnology	3	0	0	3	I
9	MB1139	Tissue Engineering	3	0	0	3	I
10	MB1140	Advances in Animal Biotechnology	3	0	0	3	I
11	MB1141	Biofuels and Platform Chemicals	3	0	0	3	I
12	MB1142	Food Processing and Biotechnology	3	0	0	3	I
13	MB1143	Molecular Diagnostics	3	0	0	3	I
14	MB1144	Pharmaceutical Biotechnology	3	0	0	3	I
15	MB1145	Research Methodology In Biotechnology	3	0	0	3	I
16	MB1231	Advanced Genomics and Proteomics	3	0	0	3	II
17	MB1232	Advanced Plant Biotechnology	2	0	2	3	II
18	MB1233	Advances in Molecular Pathogenesis	3	0	0	3	II
19	MB1234	Bioprocess Plant Design, Economics and Practice	3	0	0	3	II
20	MB1235	Computational Methods In Fluid Dynamics	3	0	0	3	II
21	MB1236	Marine Biotechnology	3	0	0	3	II
22	MB1237	Biogenerics and Biopharmaceuticals	3	0	0	3	II
23	MB1238	Clinical Trials	3	0	0	3	II
24	MB1239	GMP and validation in Bioprocess industries	3	0	0	3	II
25	MB1240	Human Heredity and Genetics	3	0	0	3	II
26	MB1241	Molecular Medicine and Mechanism	3	0	0	3	II
27	MB1242	Principles of Intellectual Property Rights	3	0	0	3	II

OPEN ELECTIVE (OFFERING TO OTHER PG DEPARTMENT)

S. No.	COURSE CODE	COURSE TITLE	CATE GORY	TOTAL CONTACT PERIODS	L	T	P	C
1	OMB151	Fundamentals of Nutrition	OE	3	3	0	0	3
2	OMB152	Lifestyle Diseases	OE	3	3	0	0	3
3	OMB153	Principles of Food Preservation	OE	3	3	0	0	3

EMPLOYABILITY ENHANCEMENT COURSES (EEC)

S. No.	COURSE CODE	COURSE TITLE	CATEGORY	TOTAL CONTACT PERIODS	L	T	P	C
PROJECT								
1	MB1321	Project Phase - I	EEC	12	0	0	12	6
2	MB1421	Project Phase - II	EEC	24	0	0	24	12

SUMMARY:

Category	SEM 1	SEM 2	SEM 3	SEM 4	TOTAL
Foundation Course	4	-	-	-	4
Professional Core Course	12	12	6	-	30
Professional Elective Course	9	6	-	-	15
Open Elective	-	3	-	-	3
Employability Enhancement Course	-	-	6	12	18
Online Course	-	3	-	-	3
Total Credits	**25**	**24**	**12**	**12**	**73**

MA1105 APPLIED STATISTICS FOR BIOTECHNOLOGY

L	T	P	C
3	1	0	4

OBJECTIVES:

- To learn the basic concept of probability and distribution for finding statistical parameters.
- To address the issues in biotechnology using the concepts on regression, curve fitting sampling, testing of hypothesis and design an analysis of experiments.
- To understand fundamental concepts of non-parametric statistical techniques.

UNIT I RANDOM VARIABLE AND PROBABILITY DISTRIBUTION 12

Random Variable-Discrete random variable – Continuous random variable – Properties – Moments and Moment Generating Function – Binomial – Poisson – Geometric – Uniform – Exponential – Normal Distributions – Simple Problems.

UNIT II METHODS OF CORRELATION AND CURVE FITTING 12

Bivariate distribution – Marginal and Conditional distribution – Correlation coefficient – Properties – Problems – Rank correlation – Regressions – Curve fitting by the method of least squares : Fitting curves of the form $y = ax + b$, $y = ax^2+bx+c$, $y = ab^x$ and $y = ax^b$.

UNIT III TESTING OF HYPOTHESIS 12

Sampling distributions – Type I and Type II errors – Small and large samples – Tests based on Normal, t, Chi square and F distributions for testing of mean, variance and proportions – Tests for independence of attributes and goodness of fit.

UNIT IV NON-PARAMETRIC STATISTICS 12

One sample sign test– Sign test for paired samples – Signed rank test – Rank sum test : The U-test Rank-sum test : The H-test – Test based on runs.

UNIT V DESIGN OF EXPERIMENTS 12

Completely random design–Randomized complete block design – Analysis of variance: One way and Two way classifications – Latin square design – 2^2 factorial design.

TOTAL: 60 PERIODS

COURSE OUTCOMES:

At the end of the course students will be able to

CO1: Apply the concept of the probability distributions in engineering problems.
CO2: Estimate the consistency and efficiency using correlation and curve fitting.
CO3: Apply statistical tests in testing hypothesis on various biological data.
CO4: Analyze the experimental data by applying suitable non-parametric test.
CO5: Apply the basic concepts of design of experiments in biological research.

REFERENCES :

1. Devore, J.L., 2014, "*Probability and Statistics for Engineering and Sciences*", 8th Edition, Cengage Learning Pvt. Ltd., New Delhi.
2. Freund, J.E., 2001, "*Mathematical Statistics*", 5th Edition, Prentice Hall of India.
3. Gupta, S.C. and Kapoor, V. K, 2016, "F*undamentals of Mathematical Statistics*", Sultan Chand and Sons, 14th Edition.
4. Johnson, R.A and Gupta C. B., 2011, "*Miller and Freund's Probability and Statistics for Engineers*", Pearson Education Int., Asia, 8th Edition.
5. Libschutz, S., 2010, "*Probability and Statistics*", 4th Edition, McGraw Hill, New Delhi.
6. Miller, I. and Miller, 2012, "*Mathematical Statistics*", 7th Edition, Pearson Education Inc. (10th impression).
7. Veerarajan,T., 2008, "*Probability, Statistics and Random Processes*".3rd Edition., Tata Mc Graw-Hill.

MB1101 ADVANCES IN BIOPROCESS TECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES

- To understand the design of bioprocess and bioreactors for various fermentation processes
- To provide knowledge about various fermentation products

UNITI FERMENTATION: PROCESS KINETICS & UNSTRUCTURED MODELING 9

Kinetics of cell growth& substrate utilization: Phases of growth - Unstructured kinetic models for microbial growth (Monod & modified Monod models – logistic equation); Kinetics of product formation: Luedeking Piret equation and analysis; Stoichiometry: yield & maintenance coefficients - elemental balances - heat balance - degrees of reduction balances.

UNIT II STRUCTURED MODELING OF FERMENTATION PROCESSES 11

Structured models of metabolism and growth: Compartment models - Models of cellular energetic and metabolism - Models of product formation - Age distribution model for the production of antibiotics - Single cell models - Models of plasmid expression and replication - Cybernetic model - Systematic analysis of black box stoichiometry.

UNIT III BIOPROCESS & BIOREACTOR DESIGN 11

Process: Different modes of cultivation – Batch - Continuous - Fed batch;Reactor: Design and operation of Batch and Continuous reactor;Chemostat-Turbidostat – Multistage reactors; Total cell retention cultivation; Aeration - oxygen mass transfer capability;Agitation - power consumption in aerated bioreactor;

UNIT IV ADVANCES IN THE FERMENTATION TECHNOLOGY 7

Design aspects of Disposable Materials in Bioproduction; Process monitoring through Biological Process Analytical Technology (*BioPAT);* Hybrid Modeling and Intensified DoE Strategies for enhanced production of Bioproducts;

UNITV CASE STUDIES IN FERMENTATION DERIVED PRODUCTS 7

Case studies on Production: Green chemicals (succinic acid – pigments) - algal biofuels - recombinant Insulin;

TOTAL:45 PERIODS

COURSE OUTCOMES:

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

CO1: Summarize about the process kinetics in fermentation and explain the unstructured modelling.
CO2: Compare and contrast the structured modelling with unstructured modelling.
CO3: Design the various operational modes of bioreactors and operational modes of aeration & agitation.
CO4: Make use of the advancements in fermentation technology in their future research or industry career. .
CO5: Analyse and select appropriate bioreactor configurations and operation modes based upon the nature of bioproducts and other process criteria.

REFERENCES

1. Kargi, M.S.L.F. and DeLisa, M., 2017. *Bioprocess engineering: basic concepts*. Prentice Hall.
2. Doran, P.M., 1995. *Bioprocess engineering principles*. Elsevier.
3. Clark, D.S. and Blanch, H.W., 1997. *Biochemical engineering*. CRC press.
4. Bailey, J.E. and Ollis, D.F., 1976. Biochemical engineering fundamentals. *Chemical Engineering Education*.
5. Stanbury, P.F., Whitaker, A. and Hall, S.J., 2013. *Principles of fermentation technology*. Elsevier.

MB1102 COMPUTATIONAL BIOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES

- To introduce the students to biological data and sequence analysis, phylogenetics and next generation sequencing data analysis
- To make the students get familiarized with protein three dimensional structure, modeling, docking and molecular dynamics simulations
- To understand basics concepts in Machine learning, Systems Biology approaches and informatics techniques for protein identification

UNIT I INTRODUCTION TO COMPUTATIONAL BIOLOGY AND SEQUENCE ANALYSIS 9

Molecular sequences, Genome sequencing: pipeline and data, Biological databases, Sequence Alignment, Local and Global Alignment, Needleman Wunsch Algorithm, Smith Waterman Algorithm, BLAST family of programs, Functional Annotation, Progressive and Iterative Methods for Multiple sequence alignment, Applications.

UNIT II BIG DATA IN BIOLOGY AND NEXT GENERATION

SEQUENCING DATA ANALYSIS **9**

Introduction to Big Data in Biology, GEO and SRA databases, Exome Sequencing, Single cell sequencing, Next Generation Sequence Analysis, RNA-Seq Data and Analysis, Methylome Sequence Data and Analysis, miRNA sequence data and analysis, CHiPseq data and analysis

UNIT III PHYLOGENETICS AND MODELS OF EVOLUTION **7**

Introduction to Phylogenetics, Jukes Cantor and Kimura Models of Evolution, Distance and Character based methods for phylogenetic tree construction: Unweighted Pair Group Method of Arithmetic Averages, Neighbour joining Trees, Maximum Likelihood Trees, Ultrametric and Minimum ultrametric trees, Parsimonous trees, Additive trees, Assessing the reliability of phylogenetic trees-Bootstrapping.

UNIT IV PROTEIN STRUCTURE, MODELLING AND SIMULATIONS **9**

Protein Structure Basics, Visualization, Prediction of Secondary Structure and Tertiary Structure, Homology Modeling, Protein Protein Interactions, Molecular Docking principles and applications, Molecular dynamics simulations.

UNIT V MACHINE LEARNING, SYSTEMS BIOLOGY AND OTHER ADVANCED TOPICS **11**

Machine learning techniques: Artificial Neural Networks - Applications in Protein secondary structure prediction, Hidden Markov Models for protein and gene families ; Introduction to Systems Biology, Biological Networks: Transcriptional Regulatory Networks, Protein-Protein Interaction Networks, Metabolic Networks, Signaling Networks; Regulation Networks and network motifs :Single Input Module, Dense Overlapping Regulon and Feed Forward Loops ; Microarrays and Clustering techniques for microarray data analysis, Informatics techniques for analysis of Mass spectrometry data

TOTAL:45 PERIODS

COURSE OUTCOMES:

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

CO1: Comprehend the application of different algorithms in sequence alignment tools
CO2: Outline the methodologies used for big data analysis and next generation sequencing techniques
CO3: Apply probabilistic model to determine different evolution models
CO4: Apply the utility of molecular docking, dynamic simulations studies and analyse the results
CO5: Outline the machine learning techniques, networks in Systems biology, microarray data analysis.

REFERENCES

1. Gusfield, D., 1997. *Algorithms on strings*, *trees, and sequences Cambridge University Press.* Cambridge, England.
2. Mount, D.W., 2004. *Sequence and genome analysis*. Bioinformatics: Cold Spring Harbour Laboratory Press: Cold Spring Harbour, 2.
3. Lesk, A., 2019. *Introduction to bioinformatics*. Oxford university press.

4. Leach, A.R. and Leach, A.R., 2001. *Molecular modelling: principles and applications*. Pearson education.
5. Baldi, P., Brunak, S. and Bach, F., 2001. *Bioinformatics: the machine learning approach*. MIT press.
6. Durbin, R., Eddy, S.R., Krogh, A. and Mitchison, G., 1998. *Biological sequence analysis: probabilistic models of proteins and nucleic acids*. Cambridge university press.
7. Pennington, S.R. and Dunn, M.J., 2001. *Proteomics: from protein sequence to function*. Garland Science.
8. Ye, S.Q. ed., 2016. *Big data analysis for bioinformatics and biomedical discoveries. CRC Press.*
9. Alon, U., 2019. *An introduction to systems biology: design principles of biological circuits.* CRC press.

MB1103 IMMUNOTECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES

- To Familiarize students with the applications of immunology for the development of diagnostics
- To Sensitize the students about the basic principles of vaccine development
- To Sensitize the students about the use of the knowledge of Immunotechnology for clinical applications and also become aware of the regulatory issues.

UNIT I INTRODUCTION 12

Review on Cells of the immune system and their development; primary and secondary lymphoid organs; humoral immune response; cell mediated immune responses; complement, classification of T cells and B cells, cellmarkers.

UNIT II ANTIBODIES AND ANTIBODY BASED ASSAYS 10

Development of Monoclonal antibodies, classification and their applications; ELISA – types; IFT (direct and indirect) Agglutination tests; Antigen detection assay; Plaque Forming Cell Assay, Development of rapid immunodiagnostics - Immuno- lateral flow / flow through assays. Diagnosis of immediate and delayed hypersensitivity, anaphylactic reaction, total Ig and antigen specific IgE antibody assay, assay for haemolytic diseases, assay for immune complex, skin tests for DTH response

UNIT III DEVELOPMENT OF IMMUNO ASSAYS 12

PBMC separation from the blood; identification of lymphocytes based on CD markers; FACS; Lympho proliferation assay; Mixed lymphocyte reaction; Cr51 release assay; macrophage cultures; cytokine bioassays- IL2, gamma IFN, TNF alpha.; HLA typing.

UNIT IV VACCINE TECHNOLOGY 6

Principles of vaccine development, types; Development of vaccines for bacterial, viral and parasitic diseases, Regulatory requirements for vaccine development and testing, ethical issues, protein based vaccines; sub-unit vaccines, DNA vaccines; Plant based vaccines; recombinant antigens as vaccines; reverse vaccinology, cancer vaccines, customized therapeutic cancer vaccines, (scFv) antibodies and molecular evolution of scFv for enhanced sensitivity and specificity,

UNIT V DEVELOPMENT OF IMMUNO THERAPEUTICS 5

Development of effective immuno drug targets for infectious diseases, engineered antibodies; catalytic antibodies; idiotypic antibodies; dendritic cells based immunotherapy, combinatorial libraries for antibody isolation, CAR T-cell therapy, Immune check point inhibitors.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

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

CO1: Organize the role of immune cells and their mechanism in body defense mechanism
CO2: Identify various immunological techniques that include antigen-antibody interactions and Antibody Production
CO3: Apply basic techniques for identifying antigen antibody interactions and developing immunoassays
CO4: Identify recent developments towards new or improved vaccines production & develop strategy to design novel vaccine.
CO5: Apply the technology for the development of immunotherapeutics and diagnosis

REFERENCES

1. Roitt, Ivan. 2017., *Essential Immunology* 9th Edition., Blackwell Scientific, 13th edition
2. Male D., Brostoff J. Rohn DM and Roitt I. 2012.,*Immunology, 8th ed*. Saunders
3. Goldsby , R.A., Kindt, T.J., Osbome, B.A. and Kuby J.2006. Immunology, 6th ed., W.H. Freeman
4. Casey Weaver ,Kenneth M. Murphy.,2017.*Janeway's Immunobiology*, Ninth Edition.
6. Delves, P.J., Martin, S.J., Burton, D.R. and Roitt, I.M., 2017. *Roitt's essential immunology*. John Wiley & Sons.
7. Thao Doan, Roger Melvord, Susan Viselli and Carl Walter Baugh. 2012.*Lippincott Illustrated Reviews*: Immunology, 2nd ed.
8. Punt J, Stranford S, Jones P, Owen JA.,, 2019.KubyImmunology .Eighth Edition , Macmillan Higher EducatioNn.

MB1111 **ADVANCED BIOCHEMISTRY AND MICROBIOLOGY LABORATORY**

L	T	P	C
0	0	6	3

OBJECTIVES:

- To familiarize the principles behind the qualitative and quantitative estimation of bio molecules and laboratory analysis of the same from biological components.
- To have a practical hands on experience on Absorption Spectroscopic methods and to validate spectrometric and microscopic techniques
- To familiarize the culture technique and analysis of products from various kind of microorganisms.

EXPERIMENTS

BIOCHEMISTRY

1. Extraction and quantification analysis of Carbohydrates (Any source: Serum, Food Samples)
2. Extraction and quantification of Protein (Plants and animal samples)
3. Extraction and quantification of Lipids from biological samples (Plants, Microorganisms).
4. Separation of amino acids and lipids by TLC.
5. 2D Gel Electrophoresis – Separation of Proteins (Demo)
6. Extraction and characterization of photochemical using UV-visible spectrophotometer.
7. DNA determination by UV-Visible spectrophotometer – hyper chromic effect

MICROBIOLOGY

1. Screening of Desired Microorganisms from environmental samples.
2. Screening and detection of probiotic bacteria from fermented foods.
3. Isolation and Identification of SCP Organisms – Algae, Fungi
4. Spoiled food analysis – differential media and selective media for Listeria and Clostridium.
5. Antimicrobial Efficacy analysis – Phenol coefficient / MIC

Required Equipments:

- Microscopes, purification columns, microplate reader, UV spectrometer, PAGE apparatus, Western blot apparatus (dry/semi-dry/wet), Southern blot apparatus, centrifuge, required stains, chemicals, enzymes &consumables, 2D Gel Electrophoresis, Incubator, Laminar airflow, Anaerobic chamber

TOTAL: 90 PERIODS

COURSE OUTCOMES:

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

CO1: Demonstrate the extraction, of biomolecules from various organisms.
CO2: Apply distinguished method to quantify the biomolecules.

CO3: Strategize experiments to separate and analyze the biological components.
CO4: Perform and demonstrate isolation of microorganisms from various kinds of samples.
CO5: Analyze the microbial spoilage and efficiency of growth on antimicrobial components.

REFERENCES

1. Pingoud, A., Urbanke, C., Hoggett, J. and Jeltsch, A., 2002. "*Biochemical methods: a concise guide for students and researchers*". Weinheim: Wiley-VCH
2. Segel, I.H., 2004 "*Biochemical Calculations: How to Solve Mathematical Problems in General Biochemistry*", 2nd Edition, John Wiley & Sons.
3. Wilson, K. and Walker, J. eds., 2010. "*Principles and techniques of biochemistry and molecular biology*". Cambridge university press.
4. Benson, H.J., 2002. "*Microbiological applications. Laboratory Manual in General Microbiology*". 8th ed. McGraw Hill, New York, USA,
5. James, C. and Natalie, S., 2014. "*Microbiology. A laboratory manual". Pearson Education.*

SEMESTER II

MB1201 ADVANCED GENETIC ENGINEERING

L	T	P	C
3	0	0	3

OBJECTIVES

- To understand the gene cloning methods and the tools and techniques involved in gene cloning and genome analysis and genomics.
- To explain the heterologous expression of cloned genes in different hosts, production of recombinant proteins and PCR techniques.
- To understand comparative genomics and proteomics.

UNIT I CLONING WITH SPECIAL PURPOSE VECTORS 9

Vectors and their properties; M13 based vectors; Production of RNA probes and interfering RNA; Controllable promoters for maximal expression of cloned gene – λP_L, trc, T_7 and pBAD; Factors affecting the expression of cloned genes; Purification tags for purification of cloned gene product; Vectors for solubilization of expressed proteins; Gateway system of transferring DNA fragments to vectors.

UNIT II cDNA LIBRARY CONSTRUCTION 9

OligodT priming, self priming and its limitations; Full length cDNA cloning – CAPture method and Oligo capping; Screening strategies – Hybridization, PCR, Immunoscreening, South-western and North-Western; Functional cloning – Functional complementation and gain of function; Difference cloning - Differential screening, Subtracted DNA library, Differential display by PCR.

UNIT III MUTAGENESIS AND ALTERED PROTEIN SYNTHESIS 9

Random mutagenesis **-** Error-prone PCR, Rolling circle error-prone PCR, use of mutator strains, temporary mutator strains; Insertion mutagenesis - ethyl methanesulfonate, DNA Shuffling; Signature tagged mutagenesis and Transposon mutagenesis; Site-directed mutagenesis; Incorporation of unnatural amino acids into proteins; Phage and cell-surface display for selection of mutant peptides.

UNIT IV GENOME ENGINEERING 9

DNA damage – sources and types; DNA double stranded break repair mechanisms; Engineered nucleases in genome engineering - meganucleases, ZFNs, TALEN and CRISPR-Cas system: mechanisms and applications; Benefits of genome engineering – targeted gene mutation, creating chromosome rearrangement, studying gene function with stem cells, transgenic animals, endogenous gene labelling and targeted transgene addition; Genome engineering -prospects and limitations.

UNIT V GENETIC MANIPULATION OF CELLS AND ANIMALS 9

Overview of principle of gene transfer; Methods of gene transfer to animal cell culture; Selectable markers for animal cells; Isolation and manipulation of mammalian embryonic stem cells; Using gene transfer to study gene expression and function; Creating disease models using gene transfer and gene targeting technology - Potential of animals for modeling human disease

TOTAL: 45 PERIODS

COURSE OUTCOMES:

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

CO1: Explain the role of special cloning vectors in various applications.
CO2: Distinguish between different methods of cDNA library construction and screening.
CO3: Apply mutagenesis methods in altered protein synthesis applications.
CO4: Experiment with fundamentals of genome engineering.
CO5: Apply the methods of gene transfer in animal cells.

REFERENCES

1. Krebs, J.E., Goldstein, E.S. and Kilpatrick, S.T., 2017. *Lewin's genes XII*.Jones & Bartlett Learning.
2. Brown, T.A., 2016. *Gene cloning and DNA analysis: an introduction*. John Wiley & Sons.
3. Patten, C.L., Pasternak, J.J. and Glick, B.R., 2010. *Molecular Biotechnology: Principles and Applications of Recombinant DNA*. ASM International.
4. Green, M.R., Hughes, H., Sambrook, J. and MacCallum, P., 2012. Molecular cloning: a laboratory manual. In *Molecular cloning: a laboratory manual* (pp. 1890-1890).
5. Primrose, S.B. and Twyman, R., 2013.*Principles of gene manipulation and genomics*.John Wiley & Sons.
6. Winnacker, E.L., 1987. *From genes to clones: introduction to gene technology*. VCH Verlagsgesellschaft.
7. Sivanandhan, G., Selvaraj, N., Lim, Y.P. and Ganapathi, A., 2016. *Targeted Genome Editing Using Site-Specific Nucleases, ZFNs, TALENs, and the CRISPR/Cas9 system*. Takashi Yamamoto (ed.)

MB1202 **BIOSAFETY AND BIOETHICS**

L	T	P	C
3	0	0	3

OBJECTIVES

- To familiarize the students to understand the basic definitions of biosafety, bioethics, biopolicy and good laboratory procedure and practices,
- To acquaint the students to various standard operating procedures for biotechnology research,
- To sensitize the students about legal and institutional framework for biosafety in national and international levels and knowledge about various agreements and protocols for biosafety.

UNIT I SAFETY COMPONENTS IN INDUSTRIES AND RESEARCH LABORATORIES 9

Need for safety in industries and research laboratories; – Biosafety issues in biotechnology. Biological Safety Cabinets, Primary Containment for Biohazards. Biosafety Levels - Levels of Specific Microorganisms, Infectious Agents and Infected Animals.

UNIT II SAFETY PROCEDURE AND CASE STUDIES 9

Biosafety Guidelines: Guidelines and regulations (National and International including Cartegana Protocol) – operation of biosafety guidelines and regulations;Roles of Institutional Biosafety Committee, RCGM, GEAC etc. for GMO applications in food and agriculture. Safety procedures during the environmental release of GMOs - Risk - Analysis, Assessment, management and Communication. Case Studies –SARS and COVID'19 Pandemic outbreak.

UNIT III RISK ANALYSIS 9

Overall risk analysis-emergency planning-on site & off-site emergency planning, risk management ISO 14000, EMS models case studies. Quantitative risk assessment – rapid and comprehensive risk analysis; Risk due to Radiation, explosion due to over pressure, jet fire-fire ball.

UNIT IV RESPONSIBILITIES AND RIGHTS 9

Introduction to ethics and bioethics, framework for ethical decision making. Ethical, legal and socioeconomic aspects of gene therapy, germ line, somatic, embryonic and adult stem cell research. Ethical implications for creating GM crops, GMO's, human genome project, human cloning, designer babies, biopiracy and biowarfare. Animal right activities. Ethical limits of Animal use. Green peace - Human Rights and Responsibilities: Professional Rights – Employee Rights – Intellectual Property Rights (IPR) -Discrimination.

UNIT V GLOBAL ISSUES 9

Multinational Corporations – Business Ethics - Environmental Ethics – Computer Ethics - Role in Technological Development – Weapons Development – Engineers as Managers – Consulting Engineers – Engineers as Expert Witnesses and Advisors – Honesty – Moral Leadership – Sample Code of Conduct.

TOTAL :45 PERIODS

COURSE OUTCOMES:

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

CO1: Demonstrate the importance of safety components in industries and research laboratories
CO2: Customize the safety procedure according to the Cases
CO3: Illustrate and assess the risk
CO4: Classify the responsibilities and rights
CO5: Investigate various global issues

REFERENCES

1. Fawatt, H.H. and Wood, W.S., 1965 *Safety and Accident Prevention in Chemical Operation*, Wiley Interscience,.
2. Marcel, V.C., 1987. *Major Chemical Hazard*- Ellis Harwood Ltd., Chi Chester, UK.
3. Skeleton, B., 1997.*Process Safety Analysis: An introduction*, Institution of chemical Engineers, U.K.
4. Hyatt, N.,2004.*Guidelines for process hazards analysis, hazards identification & risk analysis*,Dyadem Press,
5. Mike Martin and Roland Schinzinger, 2005. *Ethics in Engineering*, McGraw Hill,
6. New York.
7. Charles E Harris, Michael S Pritchard and Michael J Rabins, 2000."*Engineering Ethics – Concepts and Cases*", Thompson Learning.
8. Rajmohan Joshi (1st Ed.). 2006. *Biosafety and Bioethics*. Isha Books, Delhi.

MB1203 BIOSEPARATION TECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES:

- To impart knowledge on selection criteria of different separation methods based on the purity requirements of the bioproducts.
- To outline the methods available for separation of insoluble from fermentation broth
- To acquire knowledge in different methods to concentrate bioproducts
- To familiarize the chromatographic techniques to obtain pure proteins, enzymes and in general about product development R &D

UNIT I DOWNSTREAM PROCESSING IN BIOTECHNOLOGY 9

Role and importance of downstream processing in biotechnological processes, requirements of bio product purification. Economics of downstream processing in Biotechnology, cost-cutting strategies. Separation characteristics of proteins and enzymes: size, stability, properties. Process design criteria for various classes of bio products (high volume, low value products and low volume, high value products).

UNIT II PHYSICO-CHEMICAL BASIS OF BIO-SEPARATION PROCESSES 9

Cell disruption methods for intracellular products: Physical, chemical, mechanical. Separation techniques for the removal of insoluble: biomass and particulate debris. Filtration: Types of filtration, centrifugal and cross – flow filtration, Types of filtration equipment, Filtration at constant pressure and at constant rate, Empirical equations for batch and

continuous filtration. Centrifugation: Basic principles, design characteristics, Types of centrifuges and applications. Settling and sedimentation.

UNIT III MEMBRANE SEPARATIONS AND ENRICHMENT OPERATIONS 9

Theory, Design and configuration of membrane separation processes, Structure and characteristics of membranes, Membrane module. Reverse osmosis, microfiltration, ultra filtration, dialysis and pervaporation. Enrichment Operations: Extraction - equipment for extraction, Aqueous two-phase extraction process, Adsorption isotherms and techniques. Protein precipitation: Methods of precipitation.

UNIT IV MECHANISM AND MODES OF CHROMATOGRAPHIC SEPARATION 9

Chromatography: Classification of chromatographic techniques, General description of column chromatography, Chromatographic terms and parameters. Practice of chromatography: Partition, normal-phase, reversed-phase, size exclusion, ion exchange, hydrophobic chromatography. Affinity Chromatography: preparation of affinity matrix. Chiral chromatography, Ion chromatography. Scale-up of chromatography: Process considerations in Preparative liquid chromatography and HPLC.

UNIT V FINISHING OPERATIONS AND FORMULATIONS 9

Drying: Mechanism, methods and applications; Types of dryers: Tray, spray, rotary, belt, disc. Evaporation: types of evaporator. Freeze drying: Principle, process, applications. Crystallization: Nucleation, growth; Types of crystallizers: Tank, scrapped surface, Oslo, Circulating-magma. Case studies- Citric acid, Penicillin, Cephalosporin, Recombinant Streptokinase, Interferon.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

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

CO1: Analyze the biochemical characteristics of bioproducts and choose strategy for purification based on its purity requirements.
CO2: Comprehend the principle of separating insoluble solids from fermentation broth
CO3: Select appropriate methods to enrich the biomolecules
CO4: Design strategy for purification of bioproducts using chromatography
CO5: Distinguish different methods available in polishing of bioproducts

REFERENCES

1. Belter, P.A.,Cussler, E.L. and Hu, W., 2011,"*Bioseparations: downstream processing for biotechnology*", John Wiley and Sons.
2. Forciniti, D., 2008 ,"*Industrial Bioseparation: Principles & Practice*", Blackwell.
3. Ghosh, R., 2006. "*Principles of Bioseparations Engineering*", World Scientific Publishers,
4. Ladisch, M.R., 2001, "*Bioseparations Engineering: Principles, Practice, and Economics*", John Wiley & Sons.
5. Roger, H., 2006 ,"*Bioseparations Science and Engineering*", Oxford University Press.

MB1211 **IMMUNOTECHNOLOGY LABORATORY**

L	T	P	C
0	0	6	3

OBJECTIVES

- To make the students skilled in the fundamental techniques in immunology
- To equip them with the latest techniques required for developing skills in Immunotechnology

LIST OF EXPERIMENTS

1. Ethics, selection and handling of animals for immunological experiments (Eg. Mice, Rats, Rabbits).
2. Preparation of antigens for immunisation and Routes of immunisation (Eg. Intra-peritonial, Sub-cutaneous,Intra-muscular,Intra-nasal).
3. Methods of bleeding (Eg. Tail bleeding, Intravenous, intraorbital) (Virtual Lab Based Teaching : Hands on only on renewal / obtaining of CPCSEA license approval)
4. Collection of serum, storage and purification of total IgG (salt precipitation; ProteinA).
5. Evaluation of Antibody titre by direct ELISA.
6. Evaluation of Antigen by Sandwich ELISA.
7. Characterization of antigens by native,SDS-PAGE.
8. Characterization of antigens by Immunoblotting.
9. Conjugation of Immunoglobins (Streptavidin/colloidal gold/enzyme conjugation).
10. Methods for prototype development of Immunodiagnostics (Lateral flow or rapid immunoflow- through assays).
11. Identification of leucocytes by Giemsa stain from blood smear.
12. Outline the process of monoclonal antibody production (batch demonstrations)
13. Screening of lymphocytes by FACS
14. Separation of mononuclear cells by Ficoll-Hypaque.
15. Separation of spleenocytes and proliferation against mitogens (MTT assay) (abattoir specimens or voluntary specimens from research projects under CPCSEA guidelines and the procedure will be demonstrated).

TOTAL :90 PERIODS

Required Equipments:

- Microscopes, Microplate reader and washer, UV spectrometer, PAGE apparatus, Southern blot apparatus, centrifuge, required stains, chemicals, enzymes &consumables, Incubator, Laminar airflow.

COURSE OUTCOMES:

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

CO1: make use of the understanding of the experimental aspects of immunotechnology
CO2: acquire basics skills for the development of immunotherapeutics and diagnosis
CO3: Plan and demonstrate ability in designing immunotechnology experiments and interpretation

REFERENCES

1. Greenfield, E.A. ed., 2013. *Antibodies: a laboratory manual*. Cold Spring Harbor Laboratory Press.
2. Sambrook, J., 2001. *Molecular cloning: a laboratory manual/Joseph Sambrook, David W. Russell.*
3. Coligan, J.E., Kruisbeek, A.M., Margulies, D.H., Shevach, E.M. and Strober, W., 2003. *Current protocols in immunology*. Hoboken.

MB1311 ADVANCED GENETIC ENGINEERING LABORATORY

L	T	P	C
0	0	6	3

OBJECTIVES

- To provide hands-on experience in performing basic recombinant DNAtechniques.
- To understand the principle behind each techniques and applications of each methodology in applied biological research.
  1. Isolation of DNA
  2. Electroporation of Yeast
  3. Isolation of RNA
  4. cDNA synthesis
  5. Primer designing
  6. Real-time PCR
  7. Plasmid isolation and confirming recombinant by PCR and RE digestion.
  8. Confirmation of the presence of insert by colony PCR
  9. Induction and expression of recombinant protein
  10. Western blot with ECL detection
  11. Site directed mutagenesis
  12. Southern blot(Non-radioactive)
  13. RFLP analysis of the recombinant DNA

Required Equipments:

- Microscopes, PCR, purification columns, microplate reader, UV spectrometer, PAGE apparatus, Western blot apparatus (dry/semi-dry/wet), Southern blot apparatus, centrifuge, Haemocytometer, required stains, chemicals, enzymes &consumables

TOTAL : 90 PERIODS

COURSE OUTCOMES:

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

CO1: Apply the main principles, methods for preparation and cloning of DNA in various organisms.
CO2: Make use of gene amplification and methods for analysis of DNA, such as hybridization, restriction analysis and gene expressions for rDNA based research.
CO3: Make use of genetic and biotechnological techniques to manipulate genetic materials.
CO4: Develop new and improved recombinant organisms.
CO5: Examine the genetically modified organisms using advanced rDNA techniques.

REFERENCES

1. Green, M.R., Hughes, H., Sambrook, J. and MacCallum, P., 2012. *Molecular cloning: a laboratory manual.* In *Molecular cloning: a laboratory manual* .

MB1312 INTEGRATED BIOPROCESS LABORATORY

L	T	P	C
0	0	6	3

OBJECTIVES

- To understand the fundamentals of bioprocessing of products (Eg. industrial enzymes etc.,)
- To enrich the skills required for the steps involved from basic characterization to commercialization of bioproducts

LIST OF EXPERIMENTS

1. Enzymes: MM & inhibition kinetics, factors affecting reaction pH, temp.
2. Immobilsed of enzymes & its kinetics.
3. Bioprocess media optimization techniques – PlackettBurman, Response surface methodology.
4. Bioreactor studies : Sterilization kinetics, kLa determination, residence time distribution, sensors for bioprocess monitoring
5. Batch cultivation: Growth rate, Substrate utilization kinetics, Product analysis
6. Fed batch cultivation: Growth rate, Substrate utilization kinetics, Product analysis
7. Continuous cultivation: Growth rate, Substrate utilization kinetics, Product analysis
8. Downstream Process: Cell disruption methods - Chemical & Physical methods; RIPP Strategies: Centrifugation & microfiltration - Extraction & Precipitation – Chromatographic purification – Drying: Spray & Freeze
9. Animal cell culture production: T-flask, spinner flask,bioreactor

Equipments required:

UV-Visible Spectrophotometer, Laminar Air Flow Hood, Shaking and static Incubator, Batch Reactor, Continuous Reactor, Homogeniser, Ultrasonicator, magnetic stirrer, centrifuge, Vacuum filtration unit, Chromatographic Columns(Ion exchange, Size exclusion, affinity),spray dryer, freeze dryer.

TOTAL: 90 PERIODS

COURSE OUTCOMES:

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

CO1: Relate enzyme kinetics and immobilized enzyme studies
CO2: Demonstrate the need of media formulation and mode of microbial cultivation
CO3: Perform bioreactor studies and animal cell cultivation
CO4: Show the various downstream processing techniques related to the product of interest.

REFERENCES

1. Niazi, S.K. and Brown, J.L., 2017. *Fundamentals of modern bioprocessing*. CRC Press.
2. Saha, G., Barua, A. and Sinha, S., 2017. *Bioreactors: Animal Cell Culture Control for Bioprocess Engineering*. CRC Press.
3. Biotech, A.P., 2001. *Protein purification handbook*

MB1321 **PROJECT PHASE - I**

L	T	P	C
0	0	12	6

OBJECTIVES

- To Make the students identify a problem/process relevant to their field of interest that can be carried out
- To Make them equipped to search databases and journals to collect relevant data and identify a solution
- To Plan, learn and perform experiments to verify the solution

COURSE OUTCOMES:

At the end of the course students will be able to

CO 1: Identify the field of interest towards research/industrial problems
CO 2: equip the students to search and think about logical solutions

SEMESTER IV

MB1421 **PROJECT PHASE - II**

L	T	P	C
0	0	24	12

OBJECTIVES

1. Train students to analyze a problem/ think innovatively to develop new methods/product /process
2. Make them comprehend how to find solutions/ create products economically and in an environmentally sustainable way
3. Enable them to acquire technical and experimental skills to validate the solution, analyze the results and communicate

COURSE OUTCOMES:

At the end of the project the student will be able to

CO 1: Formulate problems statement for developing new methods/solutions/processes.
CO 2: Plan experiments in a logical manner/ work out sustainability
CO 3: Execute experiments systematically and collect the data.
CO 4: Assess, interpret and communicate the results

ELECTIVES

PROFESSIONAL ELECTIVES – I

MB1131	METABOLIC PROCESS AND ENGINEERING (FOR BIOTECHNOLOGY STREAM)	L	T	P	C
		3	0	0	3

OBJECTIVES:

- To provide a quantitative basis, enzyme kinetics, for the understanding of metabolic networks in single cells and at the organ level
- To enable the students to use organisms to produce valuable substances on an industrial scale in cost effective manner

UNIT I CELLULAR METABOLISM 9

Fueling reactions – Glycolysis, fermentative pathways – TCA cycle and oxidative phosphorylation, anaplerotic pathways – Catabolism of fats, organic acids, and aminoacids - Biosynthesis of aminoacids, nucleic acids, and fatty acids. Transport Processes.

UNIT II REGULATION, MANIPULATION AND SYNTHESIS OF METABOLIC PATHWAY 9

Regulation of enzyme activity – Regulation of enzyme concentration – Regulation of metabolic networks – Regulation at the whole cell level – Metabolic pathway manipulations – Enhancement of Product yield and productivity – Extension of substrate range, product spectrum and novel products (Antibiotics, Polyketides, Vitamins) – Improvement of cellular properties – Metabolic pathway synthesis algorithm.

UNITIII ANALYSIS AND METHODS FOR THE METABOLIC FLUX 9

Metabolic flux map, Metabolic flux analysis for determined, over-determined and under-determined systems –Sensitivity analysis – Direct flux determination from fractional label enrichment – Applications involving complete enumeration of metabolite isotopomers – Carbon metabolite balances.

UNIT IV APPLICATION OF METABOLIC FLUX ANALYSIS 9

Amino acid production – Biochemistry and regulation– Metabolic flux analysis of lysine biosynthetic network and specific deletion mutants – Metabolic fluxes in mammalian cell cultures – Intracellular fluxes, validation of flux estimates by ^{13}C labeling studies – Design of cell culture media.

UNIT V ANALYSIS OF METABOLIC CONTROL AND INDUSTRIAL CASE STUDIES 9

Fundamental of Metabolic Control Analysis (MCA), Metabolic Flux Analysis (MFA), and Metabolic Pathway Analysis (MPA) and their application, Metabolic engineering examples for bio-fuel, bio-plastic and green chemical synthesis and industrial case studies.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of this course, students should be able to

CO1: Articulate various cellular metabolism
CO2: Illustrate metabolic pathway synthesis alogorithm
CO3: Adopt various approach to analyze metabolic flux
CO4: Apply metabolic flux analysis in vital biochemical pathways
CO5: Investigate the case studies with respect to Metabolic Control Analysis (MCA), Metabolic Flux Analysis (MFA), and Metabolic Pathway Analysis (MPA)

REFERENCES

1. Christiana D. Smolke, 2010 "*The Metabolic Pathway Engineering Handbook Fundamentals*", CRC Press Taylor & Francis Group,.
2. Cortossa, S., Aon, M.A., Iglesias, A.A. and Lloyd.D., 2011 "*An Introduction to Metabolic and Cellular Engineering*", 2nd Edition, World Scientific Publishing Co,
3. Curran, C.P., 2006. "*Metabolic Processes and Energy Transfers - An Anthology of Current Thought*", The Rosen Publishing group, Inc.,
4. Nielsen, J., Villadsen, J. and Liden, G., 2011. "*Bioreaction Engineering Principle*s",3rdEdition, Springer.

MB1132 **MOLECULAR CONCEPTS IN BIOTECHNOLOGY (FOR ENGINEERING STREAM)**

L	T	P	C
3	0	0	3

OBJECTIVES:

- To Familiarize students with the cell and molecular biology of both Prokaryotes and Eukaryotes.
- To acquire basic fundamental knowledge in molecular biology and become aware of the complexity of the cells.
- To emphasize the molecular mechanism of DNA replication, repair, transcription, protein synthesis and gene regulation.

UNIT I DNA, RNA AND PROTEIN SYNTHESIS 9

Structure of DNA – DNA replication, Decoding genetic information – Transcription and translation. Regulation of transcription in bacteria and eukaryotes – Non-coding RNAs.

UNIT II MANIPULATION OF GENE EXPRESSION IN PROKARYOTE 9

Regulatable promoters, fusion proteins – Construction, cleavage and use of fusion proteins – Unidirectional tandem gene arrays and translation expression vectors – Protein stability – Oxygen limitation, protease deficient host strains, bacterial hemoglobin *Vitreoscilla* sp. – Increased protein secretion – Factor Xa and bacteriocin.

UNIT III DIRECTED MUTAGENESIS AND PROTEIN ENGINEERING 9

Directed mutagenesis – Oligonucleotide-directed mutagenesis with M13 virus and plasmid DNA – PCR amplified oligonucleotide directed mutagenesis – Protein thermo stability – Addition of disulfide bonds, reduction in free sulfhydryl residues – Increasing enzyme activity – Modifying the substrate binding specificity, modifying metal cofactor requirements – Restriction modification enzymes – Zinc finger proteins.

UNIT IV TRANSGENIC ANIMALS 9

Transgenic animals – Gene transfer methods – Retroviral vector method, DNA microinjection, engineered embryonic stem cell, nuclear transfer, YAC –Applications of transgenic animals – Transgenic livestock – Production of donor organs, pharmaceuticals, disease resistant livestock – Improving milk quality and animal production traits.

UNIT V HUMAN MOLECULAR GENETICS 9

Genetic linkage and gene mapping – Genetic polymorphism, RFLP, SNP, STRP – Physical mapping of the human genome – Sequence tagged site (STS) for constructing physical maps from YAC, BAC or PAC – Genomic libraries – Transcriptional mapping – Cloning human disease genes and methods.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of this course, students should be able to:

CO1: Explain the basic structure and biochemistry of nucleic acids and proteins and discriminate between them
CO2: Outline the mechanisms and control of gene expression in prokaryotic systems
CO3: Relate the principles of different methods of mutagenesis and their effects on protein engineering
CO4: Illustrate the emerging technologies and techniques in context of Transgenic animals
CO5: Articulate the applications of molecular biology and molecular genetics in biotechnology research

REFERENCES

1. Glick, B.R. and Patten, C.L., 2017. *Molecular biotechnology: principles and applications of recombinant DNA* (Vol. 34). John Wiley & Sons.
2. Zimmerman, J., 2003. *From genes to genomes: Concepts and applications of DNA technology: Dale, Jeremy W., and von Schantz, Malcolm. Biochemistry and Molecular Biology Education*, *31*(3), pp.217-217.
3. Krebs, J.E., Goldstein, E.S. and Kilpatrick, S.T., 2017. *Lewin's genes XII*. Jones & Bartlett Learning.
4. Sandy B. Primrose and Richard Twyman., 2016. Principles of Gene Manipulation and Genomics, John Wiley and Sons Publishers, 8th Revised Edition.
5. Strachan, T. and Read, A., 2018. Human Molecular Genetics. Garland. *New York*.

MB1133 **PRINCIPLES OFCHEMICAL ENGINEERING (FOR SCIENCE STREAM)**

L	T	P	C
3	0	0	3

OBJECTIVES:

- To perform calculations pertaining to processes and operations.
- To apply various transport process such as fluid flow, heat and mass transferring biotechnological field

UNIT I FUNDAMENTALS OF CHEMICAL ENGINEERING 9

Concepts of unit operation and unit process with examples: Units and dimensions, conversion factors, dimensional analysis. Presentation and analysis of data: Mole, density, Specific gravity, Mass fraction, Mole fraction. Analysis of multicomponent system: Concentration.

UNIT II MATERIAL AND ENERGY BALANCES 9

Overall and component material balances. Material balances without chemical reactions: Material balance calculations with chemical reactions, conversion and yield, Combustion calculations. Energy balances: Entropy, latent heat, concepts of chemical thermodynamics. Relation to Vapour Liquid Equilibrium (VLE), solution thermodynamics and reaction thermodynamics.

UNIT III FLUID MECHANICS 9

Laminar and turbulent flow: Basic equations of fluid flow, continuity equations and Bernoulli's equation.Shear–Stressrelationships,Non-Newtonianfluids,frictionfactorand its calculation in laminar and turbulent flow. Measurement of fluid flow using venture meters, orifice meters, rotameters, pitottube. Operational principles of different types of pumps, compressors and valves

UNIT IV HEAT TRANSFER 9

Conduction - Concept of heat conduction, Fourier's law of heat conduction: one dimensional steady state heat conduction, equation for flat plate, hollow cylinder; Individual and overall heat transfer coefficients and relationship between them. Convection: Concept of heat transfer by convection, natural and forced convection, equations for forced convection, Operational principles of heat exchangers, double pipe heat exchangers, shell and tube heat exchangers.

UNIT V MASS TRANSFER 9

Fick's law of diffusion – Analogy with momentum and heat transfer, diffusivities of gases and liquids, diffusion in binary mixtures, Interphase mass transfer – Film theory of mass transfer, determination of volumetric mass transfer coefficient. Mass transfer equipment: Distillation, liquid extraction, gas absorption, drying.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of this course, students should be able to:

CO1: Solve problems related to units and conversions and fit the given data using the methodologies
CO2: Solve problems related to material and energy balance concepts related to biochemical processes
CO3: Solve the problems related to fluid statics, dynamics and fluid moving machineries.
CO4: Differentiate between the different modes of heat transfer, different laws and terms used for design purpose and also to design heat exchangers from experimental data.
CO5: Describe the principles of mass transfer used for industrial applications.

REFERENCES

1. Coulson, J.M. and Richardson, J.F., 2007, "*Chemical Engineering*", Vol. I, 6th Edition, Butterworth-Heinemann Ltd.,
2. Geankoplis, C.J., 2003, "*Transport Processes and Unit Operations*", Prentice Hall India.
3. McCabe, W.L., Smith, J.C., and Harriott, P., 2014, "*Unit Operations of Chemical Engineering*" 7th Edition, McGraw-Hill Higher Education.
4. Melblau, D.M. and Riggs, J.B.,2012, "*Basic Principles and Calculations in Chemical Engineering*", 8th Edition, Kindle edition.

PROFESSIONAL ELECTIVE – II

MB1134 BIOMEDICAL DEVICES

L	T	P	C
3	0	0	3

OBJECTIVES

- To familiarize students with emerging trends in medical devices
- To apply the knowledge for early detection, selection of appropriate treatment, monitoring treatment effectiveness and disease surveillance

UNIT I SENSORS AND TRANSDUCERS 12

Rationale of electronic biosensors; Essence of three types of electronic biosensors (i.e., potentiometric, amperometric, and cantilever-based sensors); Three essential metrics that define modern electronic sensors; detection time, sensitivity, and selectivity; Physics of detection time that allows one to organize every available sensor in a systematic way; Fundamental limits of detection of various classes of sensors; Opportunities and challenges of integrating sensors in a system platform.

Principles and applications of Calorimetric, Piezoelectric, semiconductor, impedimetric, based transducers; Biochemical Transducers: Electrode theory: electrode-tissue interface, metal- electrolyte interface, electrode-skin interface, electrode impedance, electrical conductivity of electrode jellies and creams

UNIT II OPTICAL SENSORS AND BIORECOGNITION SYSTEMS 9

Photo detectors, optical fiber sensors, indicator mediated transducers; General principles of optical sensing, optical fiber temperature sensors; Pulse sensor: photoelectric pulse transducer, strain gauge pulse transducer

Enzymes; Oligonucleotides Nucleic Acids; Lipids (Langmuir-Blodgett bilayers, Phospholipids, Liposomes); Membrane receptors and transporters; Immunoreceptors; Chemoreceptors.

UNIT III ELECTRODES AND IMMOBILIZATION 9

Microelectrodes, body surface electrodes, needle electrodes, pH electrode, specific ion electrodes/ Ion exchange membrane electrodes, enzyme electrodes; Reference electrodes: hydrogen electrodes, silver-silver chloride electrodes, Calomel electrodes; Enzyme immobilization; Peptide immobilization; Antibody immobilization; Oligonucleotides and Nucleic Acid immobilization; Cell immobilization; Mono-enzyme electrodes; Bi-enzyme electrodes: enzyme sequence electrodes and enzyme competition electrodes.

UNIT IV FUNDAMENTALS AND APPLICATIONS OF MICROFLUIDICS 6

Capillary flow and electro kinetics; Micro pump, Micro mixers, Micro reactors, Micro droplets, Micro particle separators; Micro fabrication techniques (different types of lithography methods); Application of micro-fluidics (e.g. Lab- in –Chip).

UNIT V CASE STUDY ON VARIOUS DIAGNOSTIC APPLICATION 9

Biomarkers: Disease and pathogen specific information, availability by sample type Applications(blood, serum, urine, sputum, saliva, stool, mucus); Specificity, sensitivity, shelf life, portability; Clinical chemistry; Test-strips for glucose monitoring; Urea determination; Implantable Sensors for long-term monitoring; Drug development and detection; Environmental monitoring; Examples of various diseases (Cancer, HIV/AIDS, Tuberculosis, Malaria, Lymphatic Filariasis, Schistosomiasis, Dengue,Chikungunya).

TOTAL : 45 PERIODS

COURSE OUTCOMES:

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

CO1: Explain the principles of biosensor classification and construction.
CO2: Make use of basic configuration/distinction of optical sensors and bio-recognition systems to understand their utility
CO3: Summarize the concepts associated with electrode selection and bio-immobilization
CO4: Relate the basic concepts and applications of microfluidics in biosensor development
CO5: Analyze through case studies the steps involved in developing diagnostic tools.

REFERENCES

1. Cunningham, A.J., 1998. *Introduction to bioanalytical sensors*. Wiley.
2. Janata, J., 2010. *Principles of chemical sensors*. Springer Science & Business Media.
3. Scheller, F.W., Schubert, F. and Fedrowitz, J. eds., 2013. *Frontiers in biosensorics I: fundamental aspects* (Vol. 80). Birkhäuser.
4. Ligler, F.S. and Taitt, C.R. eds., 2002. *Optical biosensors: present & future*. Gulf Professional Publishing.
5. Eggins, B.R., 2008. *Chemical sensors and biosensors* (Vol. 28). John Wiley & Sons.
6. Ramsay, G., 1998. *Commercial biosensors*. J. Wiley..
7. Spichiger-Keller, U.E., 2008. *Chemical sensors and biosensors for medical and biological applications*. John Wiley & Sons.
9. Berthier, J. and Silberzan, P., 2010. *Microfluidics for biotechnology*. Artech House.
10. Gomez, F.A. ed., 2008. *Biological applications of microfluidics*. John Wiley & Sons.
11. Jenkins, G. and Mansfield, C.D. eds., 2013. *Microfluidic diagnostics: methods and protocols*. Humana Press.
12. Webster, J.G., 2006. Encyclopedia of Medical Devices and Instrumentation, volume 1, University of Wisconsin–Madison, EUA, a John Wiley & Sons. Inc. publication.

MB1135 BIOPROCESS MODELING AND SIMULATION

L	T	P	C
3	0	0	3

OBJECTIVES

- To introduce the fundamental aspects of modeling of various biological systems
- To address the various modeling paradigms, based on the level of detail, the extent of data available as well as the question the model must address.
- To outline the applications of such modeling techniques

UNIT I MODELING OF BIOLOGICALSYSTEMS 9

Modeling Principles, model development from first principles. Types of kinetic model; Data smoothing and analysis; Deterministic and stochastic approaches for modeling of structured biological systems.

UNIT II MODELING OF DIFFUSION SYSTEMS (BIOFILM AND IMMOBILIZED ENZYME SYSTEMS) 9

External mass transfer, Internal diffusion and reaction within biocatalysts, derivation of finite model for diffusion-reaction systems, dimensionless parameters from diffusion-reaction models, the effectiveness factor concept, case studies; oxygen diffusion effects in a biofilm, biofilm nitrification and denitrification.

UNIT III MODELING BIOREACTOR 9

Bioreactor modelling: Ideal and non-ideal bioreactors; Stirred tank models; characterization of mass and energy transfer distributions in stirred tanks, Tower Reactor Model; Flow modeling, bubble column flow models, mass transfer modeling, structured models for mass transfer in tower reactors, process models in tower reactors, airlift models.

UNIT IV LINEAR SYSTEM ANALYSIS 9

Study of linear systems, linearization of non-linear systems; Simulation of linear models using MATLAB; Parameter estimation and sensitivity analysis; Steady state and unsteady state systems; stability analysis; Case study of recombinant protein production.

UNIT V HYBRID AND OTHER MODELING TECHNIQUES 9

Advanced modeling techniques such as fuzzy logic, neural network, genetic algorithm, hybrid systems; case studies.

TOTAL:45 PERIODS

COURSE OUTCOMES:

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

CO1: Apply the various modeling approach to the biological systems.
CO2: Develop the diffusion systems modeling in view of biofilm and immobilized enzyme
CO3: Assess the tools and techniques for the design of various bioreactors.
CO4: Apply the concept of linear steady and unsteady state bioprocess systems.
CO5: Apply the concept of advanced modeling techniques in bioprocess systems.

REFERENCES

1. Bequette, B.W. and Bequette, W.B., 1998. Process dynamics: modeling, analysis, and simulation. Prentice- Hall.
2. Elnashaie, S.S. and Garhyan, P. eds., 2003. *Conservation equations and modeling of chemical and biochemical processes.* CRC Press.
3. Heinzle, E., john Ingham and Prenosil, J.E., 2003. *Biological Reaction Engineering: Dynamic Modelling Fundamentals with Simulation Examples.* VCH.

MB1136 ENVIRONMENTAL BIOTECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES

- To understand scientific and engineering principles to treat and minimize the global environmental problems.
- To substitute the conventional treatment methods with modern biotechnology approaches.
- To implement the technologies effectively to evade the environmental issues.

UNIT I FUNDAMENTALS OF ENVIRONMENTAL BIOTECHNOLOGY 7

Microbial flora of soil - Ecological adaptations - Interactions among soil microorganisms - biogeochemical role of soil microorganisms; Bioremediation: Types & Mechanism - Biodegradation – Bio augmentation – Bio sorption – Bioleaching. Bioreactors for Bioremediation, Metabolic pathways for Biodegradation for specific organic pollutants.

UNIT II POLLUTION AND CONTROL 11

Pollution- Sources of pollutants for Air, Water (ground water, marine), Noise, Land and its characteristics- Pollution control and management- Environmental monitoring & sampling, Physical, chemical and biological methods and analysis- Air pollution- control and treatment strategies. Modes of Biological treatment methods for wastewater-aerobic digestion, anaerobic digestion, Anoxic digestion, the activated sludge process, Design and modeling of activated sludge processes, Aerobic digestion, Design of a trickling biological filter, Design of anaerobic digester.

UNIT III INDUSTRIAL WASTE MANAGEMENT 9

Industrial waste management: Dairy - Paper and Pulp – Textile - Leather, Biomedical - Pharmaceutical industrial waste management - e-waste- radioactive and nuclear power waste management- Solid waste management.

UNIT IV MODERN TOOLS OF BIOREMEDIATION 9

Molecular biology tools for Environmental management - rDNA technology in waste treatment - Genetically modified organisms in Waste management - Genetic Sensors – Metagenomics – Bioprospecting - Nanoscience in Environmental management - Phytoremediation for heavy metal pollution - Biosensors development to monitor pollution**.**

UNIT V RENEWABLE ENERGY SOURCES AND ENERGY MANAGEMENT 9

Alternate Source of Energy - Biomass as a source of energy – Biocomposting – Vermiculture- Biofertilizers - Organic farming – Biofuels – Biomineralization - Bioethanol and Biohydrogen, Bio-electricity through microbial fuel cell - energy management and safety.

TOTAL :45 PERIODS

COURSE OUTCOMES:

At the end of this course, students should be able to

CO1: Understand the interrelationship between living organism and environment.
CO2: Compare and contrast on the various pollution and treatment strategies.
CO3: Illustrate various industrial waste and its corresponding management strategies.
CO4: Implement the modern tools of biotechnology in environmental aspects of monitoring and treatment.
CO5: Choose efficient methods towards sustainable energy and environment.

REFERENCES

1. Chakrabarty K.D., Omen G.S., 1989. Biotechnology And Biodegradation, Advances In Applied Biotechnology Series, Vol.1, Gulf Publications Co., London,.
2. Metcalf and Eddy, Inc., 1991. *Wastewater engineering: Treatment, disposal and reuse. Third Edition*.,
3. Environmental Biotechnology, Forster, C. F and Waste, D.A. J. Ellis Horwood Halsted Press,
4. Biochemical Engineering Fundamentals 2nd Ed. Bailey, J. E. and Ollis, D.F. Mac Graw Hill, New York, 1986.
5. Environmental Biotechnology by Alan Scragg;Longman, 1999.
6. Bruce E. Rittmann, Eric Seagren, Brian A.Wrenn and Albert J. Valocchi, Chittaranjan Ray, LutgardeRaskin, “In-situ Bioremediation” (2nd Edition) Nayes Publication, U.S.A, 1991.
7. Old R.W., and Primrose, S.B., Principles of Gene Manipulation (3rd Edition) Blackwell Science Publication, Cambridge, 1985.

MB1137 ENZYME ENGINEERING ANDTECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES

- To impart the knowledge on principles of enzyme engineering and enzyme technology.
- To expertise various immobilization techniques and kinetics in enzyme technology.
- To familiarize the applications of enzyme technology in various field.

UNIT I INTRODUCTION TO ENZYME TECHNOLOGY 9

Enzyme as Biological catalyst: mechanism of enzyme action, active site, enzyme-substrate complex formation. Concept of activation energy. Thermodynamics of enzyme reactions: Laws of thermodynamics, coupled reaction, free energy change, relationship between ΔG and [P]/[S] ratio. Thermodynamics of oxidation-reduction reactions, oxidative phosphorylation reactions, photosynthetic phosphorylation reactions.

UNIT II ENZYME KINETICS 9

Methods for investigating the kinetics of Enzyme catalysed reactions: Simple rapid equilibrium approach (Henri, Michaelis-Menten equation), steady-state approach (Briggs and Haldane); Order of reaction. Enzyme inhibition kinetics. Multi Substrate enzymes and kinetics mechanisms; Enzyme induction, repression, covalent modification, Isoenzymes, allosteric effects. Determination of Kcat, Km, Vmax, Ki, Half Life. Effect of pH and temperature on enzyme stability and activity.

UNIT III ENZYME ENGINEERING 9

Introduction, Random and rational approach of protein engineering in enzyme technology; Directed evolution and its application in Biocatalysis; various approaches of creating variant enzyme molecules; Futuredirection of Biocatalysis: Case studies – Alcohol dehydrogenase.

UNIT IV IMMOBILIZED ENZYME TECHNOLOGY 9

Different techniques of immobilization of enzymes and whole cells; Advantages and disadvantages of immobilization; Cross linked enzymes, enzyme crystals, their use and preparation, Kinetics of immobilized enzymes, Design and operation of immobilized enzymes reactors; Retention of enzymes in a reactor, kinetics of enzyme reactors; Reactor performance with inhibition, operation of enzyme reactors; case studies; Application and future of immobilized enzyme technology

UNIT V APPLICATIONS OF ENZYMES 9

Enzymes in organic synthesis – Enzymes as biosensors – Enzymes for food, pharmaceutical, tannery, textile, paper and pulp industries – Enzyme for environmental applications- Enzymes for analytical and diagnostic applications – Enzymes for molecular biology research.

TOTAL :45 PERIODS

COURSE OUTCOMES:

At the end of this course, students should be able to

CO1: The students will be able to apply the fundamentals of thermodynamic principles in enzyme technology
CO2: The students will be able to determine various kinetic parameters for an enzyme-substrate reaction
CO3: The students will be able to elaborate the concepts of protein engineering with respect to enzyme technology
CO4: The students will be able to design and demonstrate the immobilized enzyme reactions
CO5: The students will be able to illustrate the applications of enzymes technology in various field

REFERENCES

1. Irwin H. Segel. *Biochemical Calculations: How to Solve Mathematical Problems in General Biochemistry*, 2nd revised Ed. John Wiley &Sons
2. Trevor Palmer, 2008. *Enzymes* 2nd Edition, Horwood Publishing Ltd,
3. Biotol, 1992. *Bioreactor Design & Product Yield*. Butterworth-Heinemann.
4. Stryer, L. 2019. *Biochemistry*. 9th Edition,WH Freeman. NewYork.
5. Lehninger 2017, *Principles of Biochemistry*, 7th Edition, WH Freeman, NewYork.
6. Rehm, H. & J. Reed, G., 1986. *Enzyme Technology*. Volume 7a. John Wiley &Sons.
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MB1138 **NANOBIOTECHNOLOGY**

L	T	P	C
3	0	0	3

OBJECTIVES

- To provide fundamental concepts of nanotechnology
- To use the fundamental knowledge for the application of nanotechnology to biological sciences including nanomedicine.

UNIT I NANO SCALE AND NANOBIOTECHNOLOGY 9

Introduction to Nanoscience and Nanotechnology; Milestones in Nanotechnology; Overview of Nanobiotechnology and Nanoscale processes; Physicochemical properties of materials in Nanoscales.

UNIT II FABRICATION OF NANO MATERIALS 9

Types of Nanomaterials - Quantum dots, Nanoparticles, Nanocrystals, Dendrimers, Buckyballs, Nanotubes; Gas, liquid, and solid –phase synthesis of nanomaterials; Lithography techniques - Photolithography, Dip-pen and Electron beam lithography; Thin film deposition; Electrospinning; Bio-synthesis of nanomaterials.

UNIT III PROPERTIES, MEASUREMENT AND CHARACTERIZATION OF NANO MATERIALS 9

Optical Properties -Absorption, Fluorescence and Resonance; Methods for the measurement of nanomaterials; Microscopy measurements- SEM, TEM, AFM and STM; Confocal and TIRF imaging.

UNIT IV NANOBIOLOGY AND BIOCONJUGATION OF NANOMATERIALS 9

Properties of DNA and motor proteins; Lessons from nature on making nanodevices; Reactive groups on biomolecules- DNA & Proteins; Surface modification and conjugation to nanomaterials; Fabrication and application of DNA nanowires; Nanofluidics to solve biological problems.

UNIT V NANO DRUG DELIVERYAND NANOMEDICINE 9

Properties of nanocarriers; Drug delivery systems used in nanomedicine; Enhanced Permeability and Retention effect; Blood-brain barrier; Active and passive targeting of diseased cells; Health and environmental impacts of nanotechnology.

TOTAL : 45 PERIODS

COURSE OUTCOMES:

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

CO1: Explain the basic concepts and processes of nanobiotechnology.
CO2: Distinguish between different techniques used in fabrication of nanomaterials.
CO3: Make use of the properties and methods used for characterization of nanomaterials.
CO4: Make use of various methods for fabrication and application of nanodevices.
CO5: Compare different drug delivery systems used in nanomedicine.

REFERENCES

1. Mirkin, C.A. and Niemeyer, C.M. eds., 2004.*Nanobiotechnology: Concepts, Applications, and Perspectives*. Wiley-VCH.
2. Shoseyov, O. and Levy, I. eds., 2008.*Nanobiotechnology: bioinspired devices and materials of the future*. Springer Science & Business Media.
3. Rosenthal, S.J. and Wright, D.W. eds., 2005.*Nanobiotechnology protocols* (Vol. 303). Totowa: Humana Press.
4. Sharon, M., Sharon, M., Pandey, S. and Oza, G., 2012.*Bio-nanotechnology: concepts and applications*. Ane Books.
5. Clarke, A., Eberhardt, C. and Eberhardt, C.N., 2002. *Microscopy techniques for materials science*. Woodhead Publishing.

MB1139 TISSUE ENGINEERING

L	T	P	C
3	0	0	3

OBJECTIVES

- To learn the fundamentals of tissue engineering and tissue repairing
- To acquire knowledge on clinical applications of tissue engineering
- To understand the basic concept behind tissue engineering focusing on the stem cells, biomaterials and its applications

UNITI FUNDAMENTALS OFTISSUE ENGINEERING 9

Cell cycle and its control; Mechanical properties of cells and tissues; Cell adhesion; Extracellular matrix – Glycans, laminin, fibronectin, collagen, elastin, extracellular matrix functions; Cell Signalling – Mechanics and receptors, Ligand diffusion and binding, trafficking and signal transduction;*In vitro* cell proliferation.

UNIT II STEMCELLS AND THEIR APPLICATIONS IN TISSUE ENGINEERING 7

Stem cells – Classification, Properties, Factors influencing stem cells; Use of stem cells in tissue engineering – Embryonic stem cells, mesenchymal stem cells (MSC), adult stem cells; Markers for detection of stem cells; Risks with the use of stem cells.

UNIT III BIOMATERIALS AS SCAFFOLDSFOR TISSUE ENGINEERING 12

Measurement of protein adsorption – Direct and indirect methods; fibrinogen adsorption - Displaceable and non-displaceable; Changes in protein conformation upon adsorption – Vroman effect principle to maximize the amount of fibrinogen adsorption; Devices for tissue engineering transplant cells. Natural polymers – Structural and chemical properties; Scaffold processing; Mechanical properties and biodegradability; Biocompatibility and host response; Application of scaffolds in tissue engineering.

UNIT IV MOLECULAR AGENTS AND CELL INTERACTIONS WITH POLYMERS 9

Molecular agents in tissue engineering; Controlled released of agents – Methods, in time and space; Future applications of controlled delivery – Microfluidic systems, Microfluidics and microfluidic devices; Cell interactions – Factors influencing cell interactions, Cell interactions with polymer surfaces and suspension, Cell interactions with three-dimensional polymer.

UNIT V POLYMERS AND CONTROLLED DRUG DELIVERY 9

Natural and synthetic biodegradable Polymers; Engineered tissues – Skin regeneration, Nerve regeneration, Liver, cartilage, bone; Biodegradable polymers in drug delivery; Polymeric drug delivery systems; Other applications of biodegradable polymers.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

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

CO1: Explain the properties of cell & tissue along with cell signaling.
CO2: Utilize the theories of stem cell technology for tissue engineering applications.
CO3: Select biomaterials and carry out appropriate modifications for tissue engineering applications.
CO4: Apply the methods of delivery of molecular agents for cell interactions in Tissue engineered products.
CO5: Compare the role of polymers in different clinical applications and drug delivery.

REFERENCES

1. Pallua, N. and Suschek, C.V. eds., 2010.*Tissue engineering: from lab to clinic*. Springer Science & Business Media.
2. Palsson, B., Hubbell, J.A., Plonsey, R. and Bronzino, J.D., 2003.Principles and applications in engineering series. *Tissue Engineering, CRC Press, Boca Raton, FL*.
3. Palsson, B.O. and Bhatia, S.N., Tissue Engineering 2004. *Upper Saddle River, New Jersey*, *7458*.
4. Saltzman, W.M., 2004. *Tissue engineering: engineering principles for the design of replacement organs and tissues*. Oxford university press.
5. Lee, K. and Kaplan, D. eds., 2006.*Tissue engineering I: scaffold systems for tissue engineering* (Vol. 102). Springer**.**

PROFESSIONAL ELECTIVE –III

MB1140

L	T	P	C
3	0	0	3

OBJECTIVES

- To make the students appreciate the utility of cell culture technology for modification of animal cells
- To create awareness on principles
  of utilizing recombinant cells/ transgenic animals for clinical/ industrial applications

UNIT I CELL CULTURE TECHNOLOGY 11

Culturing of cells, primary and secondary cell lines, Cell culture-Scaling up of animal cell culture-monolayer culture, suspension culture; Various bio-reactors used for animal cell culture-Roller bottle culture; Bioreactor process control, stirred animal cell culture, Air-lift fermentor, Chemostat/Turbidostat; High technology vaccines: Hybridoma technology; Cell lines and their applications

UNIT II MOLECULAR BIOLOGY OF GENE CLONING VECTORS 9

Animal viral vectors- SV40, adeno virus, retrovirus, vaccinia virus, herpes virus, adeno associated virus and baculo virus, Vector design.

UNIT III GENETIC ENGINEERING 11

Gene therapy-prospects and problems; Knockout mice and mice model for human genetic disorder; Baculovirus in biocontrol; Enzymes technology, Somatic manipulation of DNA, Nucleic acid hybridization and probes in diagnosis- preparation of probes, evaluation and applications.

UNIT IV APPLICATIONS 10

Rumen manipulation- probiotics embryo transfer technology, invitro fertilization, transgenesis- methods of transferring genes into animal oocytes, eggs, embryos and specific tissues by physical, chemical and biological methods; Biopharming - Transgenic animals (Mice, Cows, Pigs, Sheep, Goat, Birds and Insects); Artificial insemination and embryo transfer, cryopreservation and CRISPR. Cell culture- production of therapeutic proteins, antiviral vaccines, artificial meat, biopesticides-case studies

UNIT V ANIMAL ETHICS AND REGULATIONS 4

Introduction to animal ethics; Animal rights and use of animals in the advancement of medical technology; Introduction to laws and regulation regarding use of animals in research. Ethical, Legal and Social Implications, Contemporary issues.

TOTAL :45 PERIODS

COURSE OUTCOMES:

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

CO1: have a clear understanding on scaling up animal cell culture in industry
CO2: gain experience in the development of molecular tools for viral vector based gene delivery
CO3: generalise the scope and uses of genetic engineering in animal biotechnology
CO4: apply animal biotechnology knowledge in live-stock industry.
CO5: comprehend the legislations and ethics in animal usage for research

REFERENCES

1. Watson, J.D., Gilman, M., Witowski J.A and Zoller, M., 2007, *Recombinant DNA*, 3rd ed., Scientific American Books.
2. Glick, B.R. and Pasternack, J.J. 2003, *Molecular Biotechnology*, 3rd ed., ASM Press
3. Lewin, B. 2004, Genes VIII , Pearson Prentice Hall
4. Davis J.M. 2002 *Basic Cell Culture: A Practical Approach*, 2nd ed.,IRL Press
5. Freshney R.I. 2016 *Culture of animal cells: A manual of Basic Technique and specialized Applications*,7th ed., *ISBN 978-1-118-87365-6*

MB1141 BIOFUELS AND PLATFORM CHEMICALS

L	T	P	C
3	0	0	3

OBJECTIVES

- To build a solid foundation of knowledge and skills to study about the conversion and production of biomass to biofuels.
- To understand the importance of value-added products and renewable materials in context to the global and environmental needs.
- To analyze and transfer the knowledge related to the implementation of technologies in an innovative way for the enhanced production of biofuels and chemicals.

UNIT I OVERVIEW OF BIOFUELS 9

Generation of biofuels; Development of biological conversion technologies; Energy security and supply; Types of Biomass and Available Sources; Biomass Composition and Characterization; Biorenewable Resources; Pre-Processing and pretreatment; Biochemical Processing of Carbohydrate-Rich Biomass; Thermochemical Processing of biomass; Processing of Oleaginous Feedstocks; Processing of biomass into Natural Fibers.

UNIT II BIOETHANOL 9

Ethanol as transportation fuel and additive; bioethanol production from carbohydrates; engineering strains for ethanol production from variety of carbon sources to improved productivity.

UNIT III BIODIESEL 10

Chemistry and Production Processes; Vegetable oils and chemically processed biofuels; Biodiesel composition and production processes; Biodiesel economics; Energetics of biodiesel production and effects on greenhouse gas emissions Issues of ecotoxicity and sustainability with expanding biodiesel production; Biodiesel from microalgae and microbes.

UNIT IV OTHER BIOFUELSANDPLATFORM CHEMICALS 10

Biobutanol production: principles, materials and feedstock, process technologies Biopropanol – Bioglycerol− Production of bio-oils via catalytic pyrolysis Biohydrogen production; Case studies on production of C3 to C6 chemicals such as Hydroxy propionic acid, 1,3 propanediol, propionic acid, succinic acid, glucaric acid, cis-cis muconic acid Integration of biofuels into biorefineries.

UNIT V ENVIRONMENTAL AND ECONOMIC SUSTAINABILITY OF BIOFUELS 7

Environmental Impacts - Life Cycle Analysis Biofuel Economics, policies and future R&D Biofuel Economics.

TOTAL:45 PERIODS

COURSE OUTCOMES:

At the end of the course students will be able to

CO1: Underline the different generation of biofuels and different types of biomass processing.
CO2: Describe the production of bioethanol using various feedstock.
CO3: Discuss various production strategies of biodiesel.
CO4: Elaborate the production methodologies of biobutanol, biopropanol, bioglycerol, biohyrogen and other platform chemicals.
CO5: Asses an environmental **impact and economy of biofuels.**

REFERENCE

1. Luque, R., Campelo, J.and Clark, J. *Handbook of biofuels production*, Woodhead Publishing Limited 2011.
2. Gupta, V, K. and Tuohy, M, G. *Biofuel Technologies*, Springer, 2013.
3. Moheimani, N. R., Boer, M, P, M, K, Parisa A. and Bahri, *Biofuel and Biorefinery, Technologies*, Volume 2, Springer, 2015.
4. Lee, Sunggyu; Shah, Y.T. "*Biofuels and Bioenergy*". CRC / Taylor & Francis,2013.

MB1142 FOOD PROCESSING AND BIOTECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES

- To Familiarize the principles of food chemistry and the role of enzymes in food processing
- To acquire knowledge on the role of microbes in food preservation, spoilage as well as food borne infections
- To understand the role of various process technology used by food industries and to apply them

UNIT I FOOD CHEMISTRY 7

Constituents of food – contribution to texture, flavour and organoleptic properties of food; food additives – intentional and non-intentional and their functions;

UNIT II FOOD MICROBIOLOGY 9

Sources and activity of microorganisms associated with food; fermented foods; food chemicals; food borne diseases – infections and intoxications, food spoilage – causes.

UNIT III EMERGING TECHNOLOGIES IN FOOD PROCESSING & PRESERVATION 11

High pressure processing & Preservation of foods, enzyme assisted food processing & Preservation, PEF technology (Liquids and beverages processing and preservation), Non-thermal processing by radiofrequency electric fields; Chemical food preservation; Cold preservation

UNIT IV MANUFACTURE OF FOOD PRODUCTS 9

Bread and baked goods, dairy products – milk processing, cheese, butter, ice-cream, vegetable and fruit products; edible oils and fats; meat, poultry and fish products; confectionery, beverages; Food Safety and Standards Authority of India (FSSAI) porcedures

UNIT V FOOD QUALITY AND CONTROL 9

Food quality Analysis - heavy metal, fungal toxins, pesticide and herbicide contamination in food; Microbial safety of food products ;Chemical safety of food products ; Good manufacturing practice; Case studies on comtemporary issues;

TOTAL :45 PERIODS

COURSE OUTCOMES:

At the end of the course students will be able to

CO1: Outline the basics of food chemistry and the role of Constituents and additives in food
CO2: Analyze importance and adverse effects of microbes in food industry
CO3: Demonstrate the scope of food processing & the principles involved in food Preservation.
CO4: Design a food product with innovative technologies
CO5: Articulate the approach to the management of product safety and quality

REFERENCES

1. Sivasankar, B., 2002. *Food processing and preservation*. PHI Learning Pvt. Ltd..
2. Coultate, T.P., 2009. *Food: the chemistry of its components*. Royal Society of Chemistry.
3. Sun, D.W., 2014. *Emerging technologies for food processing*. Elsevier.
4. Zeuthen, P. and Bøgh-Sørensen, L. eds., 2003. *Food preservation techniques*. Elsevier. (CRC press).
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6. Fellows, P.J., 2009. *Food processing technology: principles and practice*.Elsevier.(crc press).
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8. Pometto, A., Shetty, K., Paliyath, G. and Levin, R.E. eds., 2005. *Food biotechnology*. CRC Press.
9. Brennan, J.G., Butters, J.R., Cowell, N.D. and Lilly, A.E.V., 1976. *Food engineering operations* (No. Ed. 2). Applied Science Publishers Ltd..

MB1143

MOLECULAR DIAGNOSTICS

L	T	P	C
3	0	0	3

OBJECTIVES

- To Sensitize students about recent advances in molecular biology and various facets of molecular medicine.
- To utilize the techniques of molecular medicine for pre- or post-natal analysis of genetic diseases and identification of individuals predisposed to disease ranging from common cold to cancer.

UNIT I GENOME BIOLOGY: HEALTH, DISEASE DETECTION AND ANALYSIS 12

DNA, RNA and Protein: An overview; chromosomal structure & mutations; DNA polymorphism: human identity; clinical variability and genetically determined adverse reactions to drugs.

PCR: Real-time; ARMS; Multiplex; ISH; FISH; ISA; RFLP; DHPLC; DGGE; CSCE; SSCP;

Nucleic acid sequencing: new generations of automated sequencers; Microarray chips; EST; SAGE; microarray data normalization & analysis; molecular markers: 16S rRNA typing; Diagnostic proteomics: SELDI-TOF MS; Bioinformatics data acquisition & analysis.

UNIT II DIAGNOSTIC METABOLOMICS 6

Metabolite profile for biomarker detection in the body fluids/tissues under various metabolic disorders by making use of LCMS & NMR technological platforms

UNIT III DETECTION AND IDENTITY OF MICROBIAL DISEASES 9

Direct detection & identification of pathogenic-organisms :slow growing organisms , organisms for which a system of in vitro cultivation is lacking ,genotypic markers of microbial resistance to specific antibiotics.

UNIT IV DETECTION OF INHERITED DISEASES 9

Single Gene Disorder - Cystic Fibrosis, Diagnosis test; Single Gene disorder with non classical pattern of inheritance - mitochondrial mutations , Diagnosis test. Paradigm of the new mutational mechanism of the unstable triplet repeats- Fragile X Syndrome, von Hippel Lindau Disease : recent acquisition in the growing number of familial cancer syndromes

UNIT V MOLECULAR ONCOLOGY AND QUALITY ASSURANCE AND CONTROL 9

Detection of recognized genetic aberrations in clinical samples from cancer patients; types of cancer-causing alterations revealed by next-generation sequencing of clinical isolates; predictive biomarkers for personalized onco-therapy of human diseases such as chronic myeloid leukemia, colon, breast, lung cancer and melanoma as well as matching targeted therapies with patients ,preventing toxicity of standard systemic therapies. Quality oversight; regulations and approved testing.

TOTAL:45 PERIODS

COURSE OUTCOMES:

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

CO1: Infer various facts of molecular procedures and basics of genomics, proteomics and metabolomics that could be employed in early diagnosis and prognosis of human diseases.
CO2: Relate metabolic profile to metabolic disorders and the methods to detect them
CO3: Organize different approaches available for detection of microbial diseases
CO4: Identify and summarize different technique available for detection of inherited diseases
CO5: Outline the cause and detection of some of the inherited diseases and cancer using molecular diagnostics tools

REFERENCES

1. Campbell, A.M. and Heyer, L.J., 2003. *Discovering genomics, proteomics, and bioinformatics* (No. QH447 C35 2007). San Francisco: Benjamin Cummings.
2. Brooker, R. J. 2009. *Genetics: Analysis & Principles*. 7th Edition New York, NY:McGraw-Hill.
3. Glick, B.R. and Patten, C.L., 2017. *Molecular biotechnology: principles and applications of recombinant DNA* (Vol. 34). John Wiley & Sons.
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MB1144 PHARMACEUTICAL BIOTECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES

- To Equip the students with basics of pharmaceutical dosage form development
- To Educate them about the principles of applying the same for developing biopharmaceutical formulations.

UNIT I INTRODUCTION 8

Biotechnology in pharmaceutical industry, Drug discovery and Development phases; Drugs and Cosmetics ACT and regulatory aspects; Definition: Generics and its advantages; Biogenericsand Biosimilars; The role of patents in the drug industry; International Non-proprietary Names (INN) nomenclature system, Fermentation products in Pharmaceutical industry: Antibodies, Therapeutic proteins, Vitamins, Amino acids, Monoclonal Antibodies. Regulatory aspects of biotechnology-based products.

UNIT II DOSAGE FORMS: CLASSIFICATION, PRODUCTION AND APPLICATION 10

Definition of Dosage forms, Classification of dosage forms and its production (solid unit dosages – Tablets, capsules; liquids – solutions, lotions, suspension etc; semi-solid – ointments, creams, gel, suppositories, etc; Parenterals, Aerosols etc), Introduction to pharmacokinetics and pharmacodynamic principles (factors affecting the ADME process); bioavailability, bioequivalence. Stability study procedure for biopharmaceutical formulations, Effect of microheterogeneity in PK/ PD

UNIT III DRUG DELIVERY / CHARACTERISATION OF RECOMBINANT BIOLOGICALS 9

Advanced drug delivery systems, –Delayed release, sustained release (controlled release, prolonged release), site specific release, receptor release, carrier-based drug deliverytransdermal, and types of drugtargeting. Approaches to the characterization of biosimilars; Problems and advancements in characterizing recombinant biologics(Types of biologic, Peptides, Non-glycosylated proteins, Glycosylated proteins, Monoclonal antibodies); Equivalence issues of biologics;

UNIT IV PHARMACOLOGICAL PRINCIPLES AND MECHANISM OF DRUG ACTION 10

Understanding principles of pharmacology, pharmacodynamics kinetics and mechanism of few classes of therapeutics like laxatives, antacids and drugs used in peptic ulcers, drugs used in coughs and colds, analgesics, contraceptives, antibiotics (folate inhibitors, protein synthesis inhibitors, DNA in hibitors), hormonal agonists and antagonists, anticancer drugs.

UNIT V CASE STUDIES ON BIOPHARMACEUTICAL PRODUCT DEVELOPMENT 8

General Pipeline of enzymes, antibodies/ vaccines, blood products, nucleic acids and cell-based therapeutics production, biopharmaceutical case studies on Erythropoietin, Insulin, Somatotropin, Interleukin-2, Interferon Granulocyte-macrophage-CSF,Factor VIII**,** Tissue plasminogen activator, Monoclonal antibodies and engineered Mabs

TOTAL :45 PERIODS

COURSE OUTCOMES:

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

CO1: Enable the students to learn the principles of drug development, and regulations
CO2: Have insight about formulation of dosage forms and characterization.
CO3: Acquire knowledge on the drug delivery methods of biologicals and its characterization
CO4: Understand the principles of drug classification, pharmacology and its applications
CO5: Acquire Knowledge on the pros and cons of important biosimilars/ biologicals

REFERENCES

1. Gareth Thomas. 2000, Medicinal Chemistry., An introduction. JohnWiley.
2. Katzung B.G. 1995,*Basic and Clinical Pharmacology*, Prentice Hall of Intl.
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4. Goodman & Gilman's.2006, *The Pharmacological Basis of Therapeutics* ,11th edition, McGraw-Hill Medical Publishing Division New York.
5. Sarfaraz K. Niazi. 2006,*Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues*, CRC Press.
6. Rodney J Y Ho, MILO Gibaldi. 2003, *Biotechnology & Biopharmaceuticals Transforming proteins and genes into drugs*, 1st Edition, WileyLiss,
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MB1145 RESEARCH METHODOLOGY IN BIOTECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES:

- To impart the knowledge of various methods of research strategy
- To familiarize the biotech research constraints and its analysis
- To emphasize the Creativity, Innovation and New Product Development

UNIT I RESEARCH AND ITS METHODOLOGIES 9

Motivation – Objective and significance of research – Research process – Observation – Axiom – Theory – Experimentation – Types of research (basic, applied, qualitative, quantitative, analytical).Research Design: Concept and Importance in Research – Features of a good research design – Exploratory Research Design – concept, types and uses, Descriptive Research Designs – concept, types. Sampling: Concepts of Statistical Population, Sample, Sampling Frame, Sampling Error, Sample Size.

UNIT II RESEARCH IN BIOTECHNOLOGY

Laboratory policy and procedure of academic research – Types of expertise and facilities required. Translational Research- Technology and product transfer research – Grant funding – Sources of literature – Interdisciplinary nature – Collaboration based research.

UNIT III EXPERIMENTAL DESIGN AND APPROACHES 9

Research direction – Understanding biotechnology research by experimentation – Strategies for experimentation – Selecting an experimental design (In-silico / In-vitro / In-vivo).Microbial characterization techniques, Enzymes and enzymatic analysis – Antibodies and immunoassays –In-vitro (cell-based assays) - Computational methods – prelude to In-vitro and In-vivo experiments.

UNIT IV RESULTS AND ANALYSIS 9

Scientific methodology in recording results – Importance of negative results – Ways of recording – Industrial requirement – Artifacts versus true results – Types of analysis (analytical, objective, subjective) and cross verification – Correlation with published results – Discussion – Hypothesis, Concept – Theory and model.

UNIT V PUBLISHING SCIENTIFIC AND TECHNICAL PAPERS 9

Use of tools / techniques for Research: methods to search required information effectively, Reference Management Software like Endnote/Mendeley. Guide to publishing scientific papers – Types of scientific and technical publications in biotechnology – Specifications – Ways to protect intellectual property – Patents – Technical writing skills – Importance of impact factor and citation index.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

Upon completion of the course The students will be able to

CO1: Design the basic framework of research process
CO2: Adapt translational research and collaborative research
CO3: Evaluate and select suitable experimental design (In-silico / In-vitro / In-vivo)
CO4: Defend the concepts with appropriate results
CO5: Apply modern tools and software while publishing research papers

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3. Kothari, C.R., "*Research Methodology: Methods and Techniques*", New Age Publications, 2008.
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PROFESSIONAL ELECTIVE – IV

MB1231 **ADVANCED GENOMICS AND PROTEOMICS**

L	T	P	C
3	0	0	3

OBJECTIVES

- To Provide advanced theoretical knowledge on the organization and function of genomes
- To Understand the principles of functional genomic analyses
- To Have knowledge on the advanced methods and approaches in proteomics.

UNIT I STRUCTURE OF GENOMES, DATABASES AND SEQUENCING 9

Organization and structure of genomes in prokaryotes, eukaryotes, and organelles (chloroplast, mitochondrion); Databases of genomes,mapping by using somatic cell hybrids, Pedigree analysis, LOD score for linkage testing, QTL mapping, Advances ingene finding and functional prediction; Chain termination and chemical degradationsequencing methods, Introduction of Next Generation Sequencing (NGS), Human Genome Project, Genome epidemiology.

UNIT II LARGE SCALE GENOMICS/ FUNCTIONAL GENOMICS ANALYSES 8

Genome-wide association (GWA) analysis; Comparative Genomic Hybridization (CGH);Massively parallel Signature Sequencing (MPSS); Whole genome shot-gun sequencing and its applications. Sequence alignment and quantification, Metagenomics and methods of metagenomics.

UNIT III TRANSCRIPTOMIC ANALYSES 9

Gene expression analysis by cDNA and oligonucleotide arrays; Micro array experimental analysis and data analysis. Methylome analysis using microarray; ChIP-on-Chip analysis. RNAi and silencing of gene expression, Bioinformatic analysis of large-scale microarray data for comparative transcriptomics.

UNIT IV SEPARATION AND PROCESSING OF PROTEINS FOR PROTEOMICS 9

Proteinextraction methods from biological samples (Mammalian Tissues, Yeast, Bacteria, and Plant Tissues); Enzymatic cleavage of proteins, 2-DE of proteins for proteome analysis; Liquid chromatography separations inproteomics (Affinity, Ion Exchange, Reversed-phase, and size exclusion);TAP tag purification method, Analysis of complex protein mixtures using Nano-liquidchromatography (Nano-LC) coupled to Mass-spectrometry analysis. Applications of NMR and X-ray crystallography in proteomics

UNIT V- MASS SPECTROMETRY AND COMPARATIVE PROTEOMICS 10

Common ionization methods for peptide/protein analysis; Introduction to simple and TANDEM mass spectrometers; MALDI-TOF and LC-MS analyses; Comparative proteomics based on globalin-vitro and in-vivo labelling of proteins/peptides followed by Mass-spectrometry: SILAC – ICAT - iTRAQ. Analysis ofposttranslational modification (PTM) of proteins; Characterization of protein interactionsusing yeast two-hybrid system and Protein microarrays; Proteomics informatics andanalysis of protein functions.

TOTAL:45 PERIODS

COURSE OUTCOMES:

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

CO1: Acquire advanced theoretical knowledge on the structure, function and related databases of genomes
CO2: Perform functional genomic analyses
CO3: Apply advanced methods and approaches in proteomics
CO4: acquire theoretical knowledge on protein processing and separation methods
CO5: understand the principles of various mass spectrometric methods and comparative proteomics

REFERENCES

1. S.P. Hunt and F. J. Livesey. 2000,"*Functional Genomics*", Oxford University press
2. N. K. Spur, B. D. Young, and S. P. Bryant. 1998, ICRF "*Handbook of Genome Analysis Volume 1 & 2*", Black well publishers
3. G. Gibson and S. V. Muse, 3rd ed.2009,"*A primer of Genome Science*", Sinauer Associates, Inc. Publishers
4. R. J. Reece. 2004,"*Analysis of Genes and Genomes*", John Wiley& Sons Ltd
5. Rinaldis E. D. and Lahm.2007, "*DNA Microarrays*". Horizon bioscience.
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8. O'Connor C. D. and Hames B. D. 2008, "*Proteomics*". Scion.
9. Schena M., Jones and Bartlett, 2005."*Protein Microarrays*".
10. Smejkal G. B. and Lazarev A. V. 2006 "*Separation methods in Proteomics*". CRC Press.

MB1232 ADVANCED PLANT BIOTECHNOLOGY

L	T	P	C
2	0	2	3

OBJECTIVES

- To Provide knowledge on the concepts of plant tissue culture and genetic engineering principles,
- To Make them aware of the status of plant transgenics and regulations
- To Enlighten them about molecular pharming and other industrial applications

UNIT I INTRODUCTION TO PLANT TISSUE CULTURE 12

Introduction - Totipotency and plasticity, Explants ; Types of Cultures - single cell, callus, cell-suspension, protoplast, leaf, root, shoot tip and meristems, embryo, anther, microspore and ovary culture ; Micropropagation - Somatic embryogenesis, organogenesis and hardening ;Cell Suspension - Liquid Cultures of Plant Cells: Initiation and maintenance of callus and suspension cultures; Bioreactors – types and principles and their applications for secondary metabolites production ;Industrial applications of tissue culture Phytopharmaceuticals: Major classes of phytochemicals (secondary metabolites) and their pharmacological properties

UNIT II PLANT TRANSFORMATION VECTORS 12

Features of a plant transformation vector, Constitutive, inducible and tissue specific promoters, terminators and regulatory elements; Selectable markers and reporter genes; Modification of heterologous gene (animals, microbes) for plant transformation - Nuclear and plastid transformation; Gene transfer Methods: Agrobacterium mediated and direct gene transfer methods; Types of Vectors : Binary vectors, Gateway vectors and RNAi vectors.

UNIT III TRANSGENIC PLANTS – CASE STUDIES 12

Transgenic Plants : Herbicide tolerance [Round Up Ready], BT crops, Golden Rice, Transgenic crops designed for tolerance to abiotic and biotic stress. Transgenic systems to derive carbohydrates , plantibodies, edible vaccines, enzymes, biopharmaceuticals, bioplastics, biofuel, silk and elastin ; Global status and bio-safety concerns for production and release of transgenic plants

UNIT IV MARKER ASSISTED CROP SELECTION AND IPR 12

Classes of Molecular Markers - Phenotypic, enzyme and molecular markers, co-dominant and dominant markers; Marker-assisted Crop selection - Linkage analysis and QTL mapping; Cultivar Improvement Using Marker-Assisted Selection – Case studies ; Intellectual Property Right issues - Plant breeders rights, copyright, trade mark and patents.

UNIT V EXPERIMENTAL APPROACHES TO PLANT BIOTECHNOLOGY 12

Preparation of media - Initiation and Organ culture - Callus induction and propagation Establishment of Cell suspension cultures - Protoplast Isolation-DNA isolation from plant tissues - Encapsulation of cells/ tissues

TOTAL: 60 PERIODS

COURSE OUTCOMES:

At the end of the course students will be able to

CO1: Comprehend the fundamentals of plant tissues culture and understand the applications in plant biotechnology
CO2: Outline the molecular mechanism behind the gene transfer using Agrobacterium other plant-based vectors
CO3: Analyze the contemporary issues about genetically modified plants and discuss the ethical issues related with them
CO4: Demonstrate the need for markers in genome analysis and plant breeding.
CO5: Apply the basic techniques of plant tissue culture

REFERENCES

1. Slater, A., Scott, N. and Fowler, M., 2014. *Plant biotechnology: the genetic manipulation of plants.* OUP Oxford.
2. Smith, R.H., 2012. *Plant tissue culture: techniques and experiments*. Academic Press.
3. Bahadur, B., Rajam, M.V., Sahijram, L. and Krishnamurthy, K.V. eds., 2015. Plant *Biology and Biotechnology: Volume I: Plant Diversity, Organization, Function and Improvement.* Springer.
4. Ricroch, A., Chopra, S. and Fleischer, S.J. eds., 2014. *Plant biotechnology: experience and future prospects*. Springer.
5. Alvarez, M.A., 2016. *Plant Biotechnology for Health*. Springer International Pu..
6. Fett-Neto, A.G. 2016. *Biotechnology of Plant Secondary Metabolism*. Springer Science and Business Media,Humana Press, New York.
7. Fett-Neto, A.G. ed., 2016. *Biotechnology of plant secondary metabolism*. Springer.
8. Henry, R.J., 1997. *Practical applications of plant molecular biology*. Garland Science.
9. Reinert, J. and Bajaj, Y.S. eds., 2013. *Applied and fundamental aspects of plant cell, tissue, and organ culture.* Springer Science & Business Media.

MB1233 ADVANCES IN MOLECULAR PATHOGENESIS

L	T	P	C
2	0	2	3

OBJECTIVES:

- To enable the students to understand about the microbial toxins and modern molecular pathogenesis
- To familiarize the students about the host pathogen interaction and identifying virulence factors
- To familiarize students about controlling pathogens by modern approaches.

UNIT I VIRAL PATHOGENESIS 9

Various pathogen types and modes of entry – Viral dissemination in the host – Viral virulence – Injuryinducedbyvirus–Hostsusceptibilityofviraldisease–Patternofinfection-Acuteinfection– Persistant infection – Latent infection – Slow infection – Methods for the study of pathogenesis – Foot and mouth disease virus, Pestiviruses, Arteriviruses, Blue tongue virus, Animal herpesviruses and Corona viruses

UNIT II FUNGAL PATHOGENESIS 9

Innate humoral immunity to fungi – Acquired cellular immunity – Mucosal immunity – Intracellular pathogenesis of *Histoplasma capsulatum*– Facultative intracellular pathogen of *Cryptococcus neoformans*– Fungal interaction with leukocytes – Fungal vaccine development – Host defence against chronic disseminated *Candidiasis* – Study fungal virulence by using Genomics – Functional genomic approaches to fungal pathogenesis.

UNIT III BACTERIAL PATHOGENESIS 9

Epidemology and Clinical disease –Clinical course and basic immunology –*In vitro* models of *Salmonella* virulence –Antibiotic resistant *Salmonella* –*Salmonella* based vaccines –*Shigella* cellular models of infection –Pathogenic *Escherichia coli* –*Vibrio cholerae*–Streptococcal disease –*Haemophilus influenza* infection.

UNIT IV MANIPULATION OF HOST CELLS AND IMMUNE FUNCTION BY VIRAL PROTEINS 9

Clinical importance of understanding host defence– Interference with cytokine and Chemokine function – impairment of host mediated killing of infected cells – inhibition of apoptosis –Immunological structure of proteins – Class I and II MHC mediated antigen – Evasion from natural killer cells. Case Study : COVID 19 Pandemic

UNIT V MOLECULAR APPROACHES TO CONTROL 9

Classical approaches based on serotyping – Modern diagnosis based on highly conserved virulence factors, immune and DNA based techniques – New therapeutic strategies based on recent findings on molecular pathogenesis – Viral Vaccines – Immune modulators – New vaccine technology.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of the course students will be able to

CO1: Organize the concepts related to Host pathogen interactions at the level of cellular and molecular networks during viral pathogenesis.
CO2: Organize the concepts related to Host pathogen interactions at the level of cellular and molecular networks during fungal pathogenesis.
CO3: Organize the concepts related to Host pathogen interactions at the level of cellular and molecular networks during bacterial pathogenesis.
CO4: Relate the molecular interactions between host and pathogens and host immune evasion by the viral proteins
CO5: Illustrate the modern therapeutic strategies developed for diagnosing various pathogens and their control

REFERENCES

1. Flint, J., Enquist, L.W., Krug, "*Principles of Virology: Molecular Biology, Pathogenesis and Control*", American Society of Microbiology,2003.
2. .Groisman, E.A. ed., 2001. *Principles of bacterial pathogenesis.* Academic Press.
3. Gyles, C.L., Prescott, J.F., Songer, J.G. and Thoen, C.O. eds., 2008. *Pathogenesis of bacterial infections in animals*. John Wiley & Sons.
4. Mettenleiter, T.C. and Sobrino, F. eds., 2008. *Animal viruses: molecular biology* (Vol. 1). Norfolk: Caister Academic Press.
5. Norkin, L.C., 2010. Virology: molecular biology and pathogenesis. ASM press.

MB1234	BIOPROCESS PLANT DESIGN, ECONOMICS AND PRACTICE	L	T	P	C
		3	0	0	3

OBJECTIVES

- To make aware about plant designing.
- To assess cost and capital investment in product development.
- To follow good manufacturing practices

UNIT I PLANT DESIGN AND DEVELOPMENT 10

Fermentor design, vessels for Biotechnology, Pressure relief system. Materials of construction and properties. Technical feasibility survey, process development, flow diagrams, utilities for plant and their design (boiler, heat exchanger and compressor)

UNIT II PIPING, PLANT LAY OUT AND GENERAL DESIGN CONSIDERATIONS 10

Various types of Piping, material of construction, their usage; Pipe lay out; Marketability of the product, availability of technology, raw materials, equipment's, human resources, land and utilities, site characteristics, waste disposal, government regulations and other legal restrictions, community factors and other factors affecting investment and productioncosts.Modern Plant Design and case Studies.

UNIT II PROCESS ECONOMICS 9

General fermentation process economics, materials usage and cost, capital investment estimate, production cost estimate, breakeven and balance sheet analysis. Two case studies – one traditional product and one recombinant product.

UNIT IV PROFITABILITY ANALYSIS AND OPTIMIZATION 9

Profitability Analysis- returns on original investment, interest rate of return, accounting for uncertainty and variations and future developments. Optimization techniques – Linear and Dynamic programming, Optimization strategies.

UNIT V GOOD MANUFACTURING PRACTICES 7

Structure – quality management, personnel, premises and equipment, documentation, production, quality control, contract manufacturing and analysis, complaints and product recall, self inspection. GLP and its principles.

TOTAL :45 PERIODS

COURSE OUTCOMES:

At the end of the course students will be able to

CO1: Design the fermentor/bioreactor and their utilities.
CO2: Develop the modern process plant as per the regulations of government.
CO3: Perform the cost estimation of bioprocess.
CO4: Analyse the profitability of the product and its optimization strategies.
CO5: Demonstrate the good manufacturing practices.

REFERENCES

1. Max, S.P., Klaus, D.T. and Ronald, E.W., 2003. *Plant design and economics for chemical engineers.* McGraw-Hill Companies.
2. Butterworth, H., 1993. *A compendium of Good Practices in Biotechnology.* BIOTOL Series.
3. Seiler, J.P., 2001.*Good Laboratory Practice: The why and How?.* Springer.
4. Lydersen, B.K., D'Elia, N. and Nelson, K.L. eds., 1994. *Bioprocess engineering: systems, equipment and facilities.* New York: Wiley.

MB1235 COMPUTATIONAL METHODS IN FLUID DYNAMICS

L	T	P	C
3	0	0	3

OBJECTIVES:

The objectives are to enable the students

- To perform calculations pertaining to processes and operations.
- To apply fluid mechanics principles to applied problems.

UNIT I GOVERNING EQUATIONS 9

Fluid flow and its mathematical descriptions; conservation laws – Continuity equations – Momentum equation, energy equation – Navier-Stokes equations – Boundary conditions, Solutions of Governing Equations – Finite difference method, Finite element method, Finite Volume Method, Euler's Equations – Non-Newtonian Constitutive Equations – Curvilinear coordinates and Transformed equations – CFD as Research tool and Design tool – Validation Strategies.

UNIT II NUMERICAL ANALYSIS 9

Solving System of Algebraic equations – Gauss Elimination, Gauss-Seidel – LU-Decomposition – Jacobi – Simpson Rule – Laplace solution – Euler's method – R-K method – Fourier analysis of first and second upwind.

UNIT III COMPRESSIBLE FLOW COMPUTATION 9

Euler equations: Conservative and non-conservative from thermodynamics of compressible flow; Scalar conservations laws – Conservation – Weak solutions – Non-uniqueness – Entropy conditions – Godunov methods – Flux vector splitting Method – Reconstruction of dependent variables – Fluxes – Preconditioning of low speed Flows – Projection methods.

UNIT IV TURBULENT FLOW COMPUTATION 9

Physical Considerations – Survey of theory and models – Relation of High – Resolution Methods and Flow Physics – Large Eddy Simulation – Standard and Implicit – Numerical Analysis of Sub grid Models – ILES Analysis – Explicit Modeling – Implicit Modeling – Limiters – Energy Analysis – Computational Examples – Burgers' Turbulence – Convective Planetary Boundary Layer.

UNIT V FINITE ELEMENT METHOD 9

Finite Element formulation – Errors, Solutions of Finite difference equations –Elliptic equations-– Parabolic Equations – Hyperbolic Equations – Burger's Equations – Nonlinear Wave equation (Convection Equation) – Primitive Variable method for Incompressible viscous flows; Taylor- Galerkin Method and Pertov-Galerkin Method for Compressible Flows.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of the course students will be able to

CO1: Demonstrate an ability to recognize the type of fluid flow that is occurring in a particular physical system and to use the appropriate model equations to investigate the flow.
OO2: Apply the differential equations for flow phenomena and numerical methods for their solution.
CO3: Undertake compressible flow computations using current best practice for model and method
selection, and assessment of the quality of results obtained.
CO4: Undertake turbulent flow computations using current best practice for model and method selection, and assessment of the quality of results obtained.
CO5: Use and develop flow simulation software on the basis of finite element method for the most important classes of flows in engineering and science.

REFERENCES

1. Blazek, J., 2015. *Computational fluid dynamics: principles and applications.* Butterworth-Heinemann.
2. Cebeci, T., Shao, J.P., Kafyeke, F. and Laurendeau, E., 2005*. Computational fluid dynamics for engineers.* Springer Berlin Heidelberg.
3. Drikakis, D. and Rider, W., 2006. *High-resolution methods for incompressible and low-speed flows.* Springer Science & Business Media.
4. Knight, D., 2006. *Elements of numerical methods for compressible flows (Vol. 19). Cambridge University Press.*

MB1236 MARINE BIOTECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES:

- Discuss about the abiotic and biotic components of the marine ecosystem.
- Discuss about the active compounds obtained from the marine environment and their applications. Explain the various techniques used in aquaculture

UNITI INTRODUCTION TO MARINE ENVIRONMENT 9

World oceans and seas – ocean currents –Types of marine environment - Physical, Chemical and Biological aspects and their interaction with marine life. Ecological divisions of the sea – history of marine biology – bioecochemical cycles – food chain and food web.

UNIT II IMPORTANT MARINE ORGANISMS 9

Phytoplanktons – Zooplantons – Nektons – Benthos – Marine mammals – Marine algae – Mangroves – Coral reefs – Deep sea animals and adaptation – Intertidal zone – Fauna and flora. Harmful Algal Blooms

UNIT III MARINE ENVIRONMENTAL BIOTECHNOLOGY 9

Marine pollution-major pollutants (heavy metal, pesticide, oil, thermal, radioactive, plastics, litter and microbial) & sources; biology indicators (marine micro, algae) – biodegradation and bioremediation – marine fouling and corrosion.

UNITI V MARINE PHARMACOLOGY 9

Medicinal compounds from marine flora and fauna – Pharmaceutical compounds: Antibiotic, Antiviral, Antitumor compounds; Health promoting products: probiotic, prebiotic, immune-stimulants, enzymes; HACCP in seafood product and Manufacture, EU food hygiene Legislation.

UNIT V AQUACULTURE TECHNOLOGY 9

Important of coastal aquaculture – marine fishery resources – common fishing crafts and gears –aqua farm design and construction - Bio-floc technology; Aquaponics; Zero water exchange aquaculture system; Aquamimicry; Hydroponics; Raceway system of aquaculture; Bioremediation in Aquaculture systems.

TOTAL: 45 PERIODS

COURSE OUTCOME:

At the end of the course students will be able to

CO-1. The students will be able to elaborate the components, interactions and their biochemical niches of marine environment.
CO-2. The student will be able to categorize the type of organisms in marine environment
CO-3. The students will be able to demonstrate/determine/describe the types of pollutants and their remediation process.
CO-4. The students will be able to summarize the variety of marine pharmacological production from different living systems.
CO-5. The students will be able to design and demonstrate different aquaculture technology.

REFERENCES

1. Fingerman. M,Nagabhushanam.R, 2000. *Recent Advances in Marine Biotechnology* (Vol.4), Science Publishers (US).
2. Proksch, P. and Müller, W.E. eds., 2006. *Frontiers in marine biotechnology*. Norfolk: Horizon Bioscience.
3. Karleskint, G., Turner, R. and Small, J., 2012. *Introduction to marine biology.* Cengage Learning.
4. CengageLearning.Fingerman, M. Nagabhushanam, R. Mary – Frances Thomson, 1999.*Recent advances in marine biotechnology* (vol: 3), Science Publisher (US).
5. Fingerman, M. Nagabhushanam, R. Mary – Frances Thomson, 1999.*Recent advances marine biotechnology*, (vol: 2), Science Publisher (US).
6. Marghany, M. 2016. *Applied Studies of Coastal and Marine Environments*. BoD–Books on Demand.

PROFESSIONAL ELECTIVE –V

MB1237 BIOGENERICS AND BIOPHARMACEUTICALS

L	T	P	C
3	0	0	3

OBJECTIVES

- To Introduce the students about biogenerics and biosimilars and their characterization using analytical methods.
- To Correlate the conceptual learning of biopharmaceuticals with their therapeutic equivalence using case studies.

UNIT I BIOGENERICS INTRODUCTION 9

Definition: Generics and its advantages; Biogenericsvs Biosimilars; Why biosimilars are not (bio) generics; The advent of Biosimilars; The role of patents in the drug industry; Protein-based biopharmaceuticals; Manufacturing processes; Global market; International Non-proprietary Names (INN) nomenclature system biosimilars regulation (Indian norms, EU position, US pathways, Government initiatives)

UNIT II BIOSIMILARS AND ITS SCENARIO 9

Approved follow-on proteins/Biosimilars; Characteristics of high selling peptides and proteins, Products with expired patents; Challenging originator's patents; Target products for FOB (follow-on biologics) /Biosimilars development peptides; Recombinant Non-Glycosylated proteins; Recombinant glycosylated proteins; Industries dealing with biogenerics and its market value; World scenario; Indian scenario.

UNIT III CHARACTERIZATION OF BIOSIMILARS 10

Approaches to the characterization of biosimilars; Problems in characterizing biologics (Types of biologic, Peptides, Non-glycosylated proteins, Glycosylated proteins, Monoclonal antibodies); Equivalence issues; product variations and effects due to Post-translational modifications; Effect of microheterogeneity; Pharmacokinetics; Pharmacodynamics; and Clinical efficacy; Analytical Methods for the characterization of biosimilars (Chromatography, Protein sequencing, Mass Spectrometry, UV absorption, Circular dichroism, X-ray techniques, Nuclear magnetic resonance, Electrophoresis, Western blotting, Bioassays, ELISA, Immunoprecipitation and other procedures)

UNIT IV IMMUNOGENICITY OF BIOPHARMACEUTICALS 8

Factors contributing to immunogenicity (product-related factors and host-related factors), consequence of immunogenicity to biopharmaceuticals; Assessment protocol for biopharmaceutical immunogenicity.

UNIT V CASE STUDIES 9

Case studies: Erythropoietin, Insulin, Somatotropin, Interleukin-2, Interferon, Granulocyte macrophage-CSF, DNase, Factor VIII, Activated protein C, Tissueplasminogen activator, Monoclonal antibodies etc.,

TOTAL :45 PERIODS

COURSE OUTCOMES:

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

CO1: Acquire knowledge about biogenerics production.
CO2: Update knowledge on current aspects of biosimilars.
CO3: Learn about production and characterization of biopharmaceuticals.
CO4: Having insight on the immune responses of biogenerics
CO5: Acquire knowledge about production, applications, pros and cons of biogenerics in market

REFERENCES

1. Niazi, Sarfaraz K. 2006, "*Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues".* CRC Press.
2. Ho, Reedney J. Y., MiloGibaldi. 2013, "*Biotechnology & Biopharmaceuticals Transforming Proteins and Genes into Drugs"*, 2nd edition.

MB1238 CLINICAL TRIALS

L	T	P	C
3	0	0	3

OBJECTIVES

- provide fundamental learning about clinical trial management in drug development and project management in clinical trials.
- learn about pharmaco vigilance, quality control and ethical management in clinical research.

UNIT I INTRODUCTION TO CLINICAL TRIALS AND REGULATIONS 9

Fundamentals of clinical trials; clinical trial terminologies, Basic statistics for clinical trials; Legislation and good clinical practice guidelines of CPCSEA – overview of CFR (FDA) and Directives of EU,ICMR Guidelines, Principles of the International Committee on Harmonisation (ICH)-GCP, Indian GCP, Clinical trial application requirements, Regulations for AYUSH, Schedule – Y- Appendices, Introduction to laws and regulations regarding the use of animals in research

UNIT II CLINICAL RESEARCH OPERATIONS 9

Drug development and trial planning - pre-study requirements for clinical trials; operation of institutional review board/ independent ethics committee, Regulatory Approvals for clinical trials; Consort statement; Trial responsibilities and protocols - roles and responsibilities of investigators, sponsors, CROs/ SMOs/ CRAs/coordinators/ and biostatician, Requirements of clinical trials protocols; Legislative requirements for investigational medicinal products, medical coding and writing.

UNIT III BIOETHICS AND MANAGEMENT OF CLINICAL TRIALS 9

Project management and E- clinical trials - principles of clinical data and clinical trial management; Risk assessment; Research ethics in clinical trials, Ethical issues in clinical trials; Use of humans in Scientific Experiments; Ethical committee system including a historical overview; Declaration of Helsinki, Introduction To ethical codes and conduct; Introduction to animal ethics; Animal rights and use of animals in the advancement of medical technology;. Nuremberg code.

UNIT IV INFORMED CONSENT 9

Consent and data protection- the principles of informed consent; Belmont Report, Consent processes; Data Protection; Legislation and its application; Data management – Introduction to trial master files and essential documents.

UNIT V QUALITY CONTROL AND GUIDELINES 9

Clinical quality management plan, Quality assurance and governance - quality control in clinical trials; Monitoring and audit; Inspections; Pharmacovigilance; Research governance; Trial closure and pitfalls-trial closure; Reporting and legal requirements; Common pitfalls in clinical trial management.

TOTAL: 45 Periods

COURSE OUTCOMES:

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

CO1: Understand the basics of clinical trial and its regulations framed by FDA, EU and India
CO2: Setup the clinical trial team and define its role for clinical research
CO3: Acquire Knowledge about the bioethics to be followed during clinical trial
CO4: understand the legal forms and data management for animal and human subjects
CO5: apply the guidelines of clinical trials for quality research

REFERENCES

1. Lee, Chi-Jen; et al., 2011, "*Clinical Trials or Drugs and Biopharmaceuticals*." CRC / Taylor &Francis.
2. Matoren, Gary M.1984, "*The Clinical Research Process in the Pharmaceutical Industry*."Marcel Dekker,

MB1239 GMP AND VALIDATION IN BIOPROCESS INDUSTRIES

L	T	P	C
3	0	0	3

OBJECTIVES

- be aware of current validation practice across the bioprocess industry
- assess new process concepts and understand regulatory acceptability for bioprocess industries
- provide knowledge to determine the information required and validate a process

UNITI PROCESS VALIDATION: GENERAL PRINCIPLES AND PRACTICES 9

General Considerations for Process Validation, Concept of Bioprocess in Bulk Drug Manufacturing, Concept of Biotechniques in industrial validation, Integration of various biotechniques to maintain quality in downstream processing, CGMP regulations for validating biopharmaceutical (drug) manufacturing.

UNIT II APPROACH TO PROCESS VALIDATION 9

Process Design, Process Qualification, Continued Process Verification, attributes relating to identity, strength, quality, purity, and potency; Information and data organization from laboratory-, pilot-, and/or commercial-scale studies, validation of computerized systems.

UNIT III TRENDS FOR VALIDATING BIOLOGICAL PROCESSES 9

Importance of process validation for manufacturing drugs and medical devices, Definitions, Process validation, Prospective Validation, Concurrent Validation, Retrospective Validation, Critical Process Parameters, Critical Quality Attributes, Scaled-down model, Worst-case, FDA Guidelines

UNITIV GOOD MANUFACTURING PRACTICE FOR BIOPROCESS ENGINEERING 9

Statutory and regulatory requirements for process validation, Production Methods and Considerations, Automation and control issues, System functionality, Principles for Layout of Bulk Production Facilities, Green Field Development, Brown Field Development, cross-contamination from other sources and linked systems, Clean In Place techniques, interactions with shared systems

UNITV CASES STUDIES IN PROCESS VALIDATION 9

Process validation for recombinant therapeutic proteins like erythropetin, insulin, GMCSF, viral, bacterial vaccines

TOTAL : 45 PERIODS

COURSE OUTCOMES:

At the end of the course students will be able to

CO1 Understand the implications of process validation for process development.
CO2 Understand the general principles and practices of process validation of biopharmaceutical manufacturing processes.
CO3 Analyze the various trends towards the validation of biological processes.
CO4 Understand manufacturing practice for bioprocess engineering
CO5 Design, verify and validate process using case studies.

REFERENCES:

1. Anurag S. Rathore, Gail Sofer, *Process Validation in Manufacturing of Biopharmaceuticals*, Third Edition, CRC Press,2012
2. Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology, 1st ed.,2010

MB1240 **HUMAN HEREDITY AND GENETICS**

L	T	P	C
3	0	0	3

OBJECTIVES

- To be aware of the fundamental aspects of human heredity
- To make them understand the factors which influence the inheritance
- To make them familiar with the tools available to test the inheritance of congenital diseases and gene therapy

UNIT I INTRODUCTION TO MENDELIAN GENETICS 9

Introduction to Genetics; Mendelian Genetics – Definitions: Alleles, Phenotypes, Genotypes, Dominance, Incomplete Dominance, co-dominance, Recessiveness, Homozygous, Heterozygous, Hemizygous , Penetrance and Expressivity; Multiple Alleles, ABO blood groups, Bombay phenotype, Epistasis, Pleitropy; Mendelian inheritance in Humans – Segregation and Independent; Assortment – Marfan Syndrome, Porphyria variegate; Prader – Willi Syndrome and Angelman Syndrome; Types of inheritance - Autosomal Recessive, Autosomal Dominant, Sex-linked Dominant and Sex-linked Recessive; Pedigree Analysis of the different types of inheritance.

UNITII CYTOGENETICS 9

Human chromosome set; Analyzing chromosomes and Karyotype; Making a karyotype and obtaining cell; Aminocentesis, Chorionic villi sampling-Variation in chromosome number of sets - Polyploidy, Aneuploidy, Autosomal Monosomy, Autosomal trisomy; Risks for autosomal trisomy; Aneuploidy of the sex chromosomes - Turner syndrome, Kleinfelter Syndrome, XYY. Structural Alterations –Deletions and translocations, Fragility and Uniparental Disomy.

UINIT III HUMAN DEVELOPMENT ANDSEX DETERMINATION 9

Sex determination in humans; Human development - Fertilization to Birth; Trimester of Birth; Teratogens, Radiation, Infections agents and Chemicals; Fatal Alcohol Syndrome; Controlling Reproduction - Contraception and Assisted Reproductive Technologies, Role of environment and chromosomes, Role of Hormones - Androgen insensitivity; Sex testing in sports, Sex phenotype changing and Sex phenotype at puberty. Mutations - Equalizing chromosomes in males and females; Mosaicism, X-inactivation, Expression genes on the X-chromosome; Sex- influenced and Sex-limited traits in humans; Mitochondrial inheritance.

UNITIV POLYGENES AND MULTIFACTORIAL INHERITANCE 9

Polygenes and Variations in phenotype; Additive model - Averaging out the phenotype for polygenic inheritance; Multifactorial inheritance and traits; Effect of the environment; Threshold effect and the expression of multifactorial traits; Interaction between genotype and the environment; Fingerprints to estimate heritability; Twins - Homo zygotic and Dizygotic; Skin color; Cardiovascular diseases-Genetics and Environment; Intelligence and IQ; Searching for genes for intelligence - IQ andRace.

UNIT V GENE MAPPING, TESTING AND BIOETHICS 9

Gene mapping; Testing; Physical mapping; Heteromorphisms, Deletions, Translocation, Dosage mapping; In-situ Hybridization, Somatic Cell hybridization, and positional cloning; Genetic testing and Gene therapy; Clinical Genetics and Genetic counseling; Eugenics and Bioethics.

TOTAL:45 PERIODS

COURSE OUTCOMES:

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

CO1: Explain the basic concepts Mendelian genetics.
CO2: Distinguish between variation in chromosome number of sets and the diseases associated with them.
CO3: Categorize the stages of human development and sex determination criteria.
CO4: Identify the fundamental aspects of multifactorial inheritance and traits.
CO5: Apply the concepts of gene mapping and genetic testing in clinical applications.

REFERENCES

1. Tamarin, R.H., 2015. *Principles of genetics*. McGraw-Hill.
2. De Robertis, E.D.P., 1980. De Robertis EMF Jr. *Cell and Molecular Biology.*
3. Simmons, M.J. and Snustad, D.P., 2006. *Principles of genetics*. John Wiley & Sons.
4. Strickberger, M.W., 1976. Genetics MacMillan Publishing Company. *New York*.
5. Palladino, M.A., Spencer, C.A., Cummings, M.R. and Klug, W.S., 2015. *Concepts of Genetics*. Pearson Higher Ed.

MB1241 MOLECULAR MEDICINE AND MECHANISM

L	T	P	C
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OBJECTIVES

- To Familiarize the students about the molecular mechanism of the disease and advanced understanding of drug interactions.
- To Familiarize the students about the molecular organization of different organ systems and its functions.

UNIT I INTRODUCTION TO MOLECULAR MEDICINE 9

Organization of the Human Genome, Chromosomes and Genes – Recombinant DNA and Genetic Techniques – Transcriptional Control of Gene Expression – transmission of Human Genetic Disease –Human Genome Project – Cell Cycle Oncogenes and Tumor suppressor Genes – Molecular Diagnostic Testing – Genetic Counseling – Transgenic Mice as Models of Disease, Introduction to gene therapy.

UNIT II CARDIOLOGY 9

Molecular Cardiology Congenital Heart Disease–Inherited Cardiomyopathies–Coronary Atherosclerosis – Endothelium – Derived Nitric Oxide and Control of Vascular Tone – Hypertension – Cardiac Arrhythmias – Cardiovascular Gene Therapy.

UNIT III PULMONOLOGY 9

Asthma – Cystic Fibrosis – Pulmonary Emphysema – Surfactant Deficiency – Lung Cancer: The Role of Tumor Suppressor Genes – Strategies for controlling the diseases.

UNIT IV ENDOCRINOLOGY 9

Mechanisms of Hormone Action – Diabetes Mellitus – Pituitary Function and Neoplasia Hormone Deficiency- Disorders –Thyroid Disorders – Disorders of the parathyroid Gland – Congenital Adrenal Hyperplasia– Adrenal Disease – Multiple Endocrine Neoplasia Type, Mechanisms of Hypoglycemia Associated with increased Insulin Production.

UNIT V NEPHROLOGY 9

Renal Development – Mechanisms of Leukocyte Extravasation – Ischemic Acute Renal Failure-Potassium Secretory Channels in the Kidney –Alport Syndrome –Nephrogenic Diabetes Insipidus –Polycystic Kidney Disease –Renal Neoplasms: Wilms'Tumor and Renal-Cell Carcinoma.

TOTAL:45 PERIODS

COURSE OUTCOMES:

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

CO1: Illustrate the human genome, molecular diagnostic testing and gene therapy.
CO2: Explain the circulatory system of the human body , disease associated with the system and their diagnosis .
CO3: Explain the respiratory system of the human body , disease associated with the system and their diagnosis .
CO4: Explain the endocrine system of the human body , disease associated with the system and their diagnosis .
CO5: Explain the excretory system of the human body , disease associated with the system and their diagnosis .

REFERENCES

1. Jameson, J.L. ed., 1998. *Principles of molecular medicine*. Springer Science & Business Media.
2. Ross, D.W., 2002. *Introduction to Molecular Medicine* Springer, New York, NY..
3. Ross, D.W., 1998. *Introduction to oncogenes and molecular cancer medicine*. Springer Science & Business Media.
4. Pasternak, J.J., 2005. *An introduction to human molecular genetics: mechanisms of inherited diseases*. John Wiley & Sons.
5. Strachan, T. and Read, A.P., 1996. Human Molecular Genetics. Bios..
6. Runge, M.S. and Patterson, C. eds., 2007. *Principles of molecular medicine*. Springer Science & Business Media.

MB1242 PRINCIPLES OF INTELLECTUAL PROPERTY

L	T	P	C
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OBJECTIVES:

- To create awareness about IPR.
- To make familiar with basics of IPR and their implications in Research, development and commercialization.
- To integrate the IPR process in their research activities.

UNIT I INTRODUCTION TO INTELLECTUAL PROPERTY RIGHTS 6

Introduction to Intellectual Property Rights, Basic concepts and need for Intellectual Property - Types of IP: Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications, Protection of GMOs, IP as a factor in R&D; IPs of relevance to Biotechnology.?

UNIT II AGREEMENTS, TREATIES AND CONCEPT OF PRIOR ACT 9

Agreements and Treaties: History of GATT & TRIPS Agreement, Madrid Agreement; Hague Agreement, WIPO Treaties; Budapest Treaty; PCT, Indian Patent Act 1970 & recent amendments, Ordinary – PCT –Conventional – Divisional and Patent of Addition – Specifications – Provisional and complete –Forms and fees Invention in context of prior art.

UNIT III CONTEMPORARY ISSUES IN IPR 9

Interface between IPR and Human Rights; Interface between IPR and Competition Law; IPR and sustainable development; The Impact of Internet on IPR; IPR Issues in Biotechnology.

UNIT IV PATENT LAWS 9

IP Laws, Cyber Law and Digital-Content Protection – Unfair Competition – Meaning and Relationship between Unfair Competition-IP Laws – Case Studies. Licensing – Voluntary & Non –Voluntary; Assignment; Fair Use; Use and acquisition of inventions by Government; Infringement of IPRs and remedies, Enforcement Measures, Emerging issues – Case Studies.

UNIT V PATENT SEARCH, DRAFTING AND FILING PROCEDURES 12

Patent databases: Searching International Databases; Country-wise patent searches (USPTO, esp@cenet(EPO), PATENT Scope(WIPO), IPO, etc.). Patent Drafting: Drafting a Claim; Types and Arrangement of Claims; Structure of the Patent Specification; Patent Filing: National & PCT filing procedure – Time frame and cost – Status of the patent applications filed –Precautions while patenting – disclosure/non-disclosure – Financial assistance for patenting –existing schemes-Patent licensing and agreement Patent infringement – Meaning, scope, litigation, case studies.

TOTAL :45 PERIODS

COURSE OUTCOMES:

At the end of the course students will be able to

CO1: underline the different types of Intellectual Properties, the right of ownership and the scope of protection.
CO2: describe the agreements, treaties and concept of prior act.
CO3: discuss various contemporary issues in IPR.
CO4: identify activities and constitute IP infringements and the remedies available to the IP owner and describe the precautious steps to be taken to prevent infringement of proprietary rights in products and technology development.
CO5: demonstrate the patent search, drafting and filing procedures.

REFERENCES:

1. Bouchoux, D.E., 2012. *Intellectual property: The law of trademarks, copyrights, patents, and trade secrets.* Cengage Learning.
2. Irish, V., 2005. *Intellectual property rights for engineers* (Vol. 22). IET.
3. Halbert, D., 2016. *Intellectual property theft and national security: Agendas and assumptions.* The Information Society, 32(4), pp.256-268.
4. Nard, C.A., 2019. *The law of patents.* Aspen Publishers.

OPEN ELECTIVE

OMB151 **FUNDAMENTALS OF NUTRITION**

L	T	P	C
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OBJECTIVES:

- The course aims to develop the knowledge of students in the basic area of Food Chemistry.
- This is necessary for effective understanding of food processing and technology subjects.
- This course will enable students to appreciate the similarities and complexities of the chemical components in foods.

UNIT I OVERVIEW OF NUTRITION 9

Definition, six classes of nutrients, calculating energy values from food, using the RDA, nutritional status, nutritional requirement, malnutrition, nutritional assessment of individuals and populations, dietary recommendations, Balanced diet planning: Diet planning principles, dietary guidelines; food groups, exchange lists, personal diet analysis;

UNIT II DIGESTION 9

Digestion, Absorption and Transport: Anatomy and physiology of the digestive tract, mechanical and chemical digestion, absorption of nutrients.

UNIT III CARBOHYDRATES 9

Glycemic and Non-glycemic carbohydrates, blood glucose regulaion, recommendations of sugar intake for health, health effects of fiber and starch intake, Artificial sweeteners; Importance of blood sugar regulation, Dietary recommendations for NIDDM and IDDM

UNIT IV PROTEINS & LIPIDS 9

Proteins; Food enzymes ; Texturized proteins; Food sources, functional role and uses in foods. Review of structure, composition & nomenclature of fats. Non-glyceride components in fats & oils; Fat replacements; Food sources, functional role and uses in foods. Health effects and recommended intakes of lipids. Recommended intakes of proteins, Deficiency-short term and long term effects.

UNIT V METABOLISM, ENERGY BALANCE AND BODY COMPOSITION 9

Energy Balance; body weight and body composition; health implications; obesity, BMR and BMI calculations; Weight Control: Fat cell development; hunger, satiety and satiation; dangers of unsafe weight loss schemes; treatment of obesity; attitudes and behaviours toward weight control. Food and Pharmaceutical grades; toxicities, deficiencies, factors affecting bioavailability, Stability under food processing conditions.

TOTAL : 45 PERIODS

REFERENCES:

1. Chopra, H.K. and P.S. Panesar. 2010*., Food Chemistry* :Narosa.
2. Vaclavik, V. A. and Christian E. W. 2003. *Essentials of Food Science*. II Edition, KluwerAcademic, Springer.
3. Mann, Jim and Stewart Truswell, 2007.*Essentials of Human Nutrition*. 3rd Edition. Oxford University Press.
4. Gibney, Michael J., et al., 2009 *Introduction to Human Nutrition*, 2nd Edition. Blackwell.
5. Gropper, Sareen S. and Jack L.Smith , 2008 .*Advanced Nutrition and Human Metabolism*. 5th Edition. Wadsworth Publishing.

OMB152 LIFESTYLE DISEASES

L	T	P	C
3	0	0	3

UNIT I INTRODUCTION 9

Lifestyle diseases – Definition ; Risk factors – Eating, smoking, drinking, stress, physical activity,illicit drug use ; Obesity, diabetes, cardiovascular diseases, respiratory diseases, cancer;Prevention – Diet and exercise.

UNIT II CANCER 9

Types - Lung cancer, Mouth cancer, Skin cancer, Cervical cancer, Carcinoma oesophagus; Causes Tobacco usage, Diagnosis – Biomarkers, Treatment

UNIT III CARDIOVASCULAR DISEASES 9

Coronoary atherosclerosis – Coronary artery disease; Causes -Fat and lipids, Alcohol abuse -–Diagnosis - Electrocardiograph, echocardiograph, Treatment, Exercise and Cardiac rehabilitation

UNIT IV DIABETES AND OBESITY 9

Types of Diabetes mellitus; Blood glucose regulation; Complications of diabetes – Paediatric and adolescent obesity – Weight control and BMI

UNIT V RESPIRATORY DISEASES 9

Chronic lung disease, Asthma, COPD; Causes - Breathing pattern (Nasal vs mouth), Smoking – Diagnosis - Pulmonary function testing

TOTAL: 45 PERIODS

REFERENCES:

1. R.Kumar & Meenal Kumar, 2003 .,Guide to Prevention of Lifestyle Diseases, Deep & DeepPublications.
2. Gary Eggar et al, 2017., *Lifestyle Medicine*, 3rd Edition, Academic Press,
3. James M.R, , 2013.,*Lifestyle Medicine*, 2nd Edition, CRC Press.
4. Akira Miyazaki et al, 2008., New Frontiers in Lifestyle-Related Disease, Springer.

OMB153 PRINCIPLES OF FOOD PRESERVATION

L	T	P	C
3	0	0	3

OBJECTIVES:

- The course aims to introduce the students to the area of Food Preservation.
- This is necessary for effective understanding of a detailed study of food processing and technology subjects.

UNIT I FOOD PRESERVATION AND ITS IMPORTANCE 9

Introduction to food preservation. Wastage of processed foods; Shelf life of food products; Types of food based on its perishability. Traditional methods of preservation

UNIT II METHODS OF FOOD HANDLING AND STORAGE 9

Nature of harvested crop, plant and animal; storage of raw materials and products using low temperature, refrigerated gas storage of foods, gas packed refrigerated foods, sub atmospheric storage, Gas atmospheric storage of meat, grains, seeds and flour, roots and tubers; freezing of raw and processed foods. retort pouch packing, Aseptic packaging.

UNIT III THERMAL METHODS 9

Newer methods of thermal processing; batch and continuous; In container sterilization canning; application of infra-red microwaves; ohmic heating; control of water activity; preservation by concentration and dehydration; osmotic methods

UNIT IV DRYING PROCESS FOR TYPICAL FOODS 9

Rate of drying for food products; design parameters of different type of dryers; properties of air water mixtures. Psychrometric chart, freezing and cold storage. freeze concentration, dehydrofreezing, freeze drying, IQF; calculation of refrigeration load, design of freezers and cold storages.

UNIT V NON-THERMAL METHODS 9

Super Critical Technology for Preservation - Chemical preservatives, preservation by ionizing radiations, ultrasonics, high pressure, fermentation, curing, pickling, smoking, membrane technology. Hurdle technology,

TOTAL: 45 PERIODS

COURSE OUTCOMES:

On completion of the course the students are expected to

- Be aware of the different methods applied to preserving foods.

REFERENCES:

1. Karnal, Marcus and D.B. Lund 2003.*Physical Principles of Food Preservation: Rutledge.*
2. VanGarde, S.J. and Woodburn. M., 2001.Food Preservation and Safety Principles and Practice,.Surbhi Publications.
3. Sivasankar, B. 2002.Food Processing & Preservation, Prentice Hall of India.
4. Khetarpaul, Neelam, 2005 .Food Processing and Preservation:, Daya Publications.