PG Diploma in Industrial Biotechnology

Syllabus

UNIVERSITY DEPARTMENT

Program Code: ****

2023 – 2023 onwards

BHARATHIAR UNIVERSITY

(A State University, Accredited with "A++" Grade by NAAC, Ranked 21st among Indian Universities by MHRD-NIRF)

Coimbatore - 641 046, Tamil Nadu, India

Program Educational Objectives(PEOs)	
The **P.G. Diploma in Industrial Biotechnology** program describe accomplishments that graduates are expected to attain within five to seven years after graduation	
PEO1	Graduate would become an expertise in industrial production process
PEO2	The candidate shall become an entrepreneur commercializing his own microbial product
PEO3	The candidate would be able to understand quality control and quality assurance in Industrial products
PEO4	The candidate would be able to establish a clinical diagnostic laboratory
PEO5	The graduate can become a bioprocess engineer designing fermentation processes

Program Specific Outcomes (PSOs)	
After the successful completion of PG. Diploma program, the students are	
PSO1	Able to perform Molecular techniques
PSO2	Design their own research problem
PSO3	Capable of culturing plant and animal cells in invitro conditions
PSO4	Capacity to design a fermentation process using a microbe
PSO5	Capable of constructing a recombinant strain for commercial purpose

Program Outcomes(POs)	
On successful completion of the PG Diploma in Industrial Biotechnology program	
PO1	The candidate is able to understand the pivotal role of the microorganism in science
PO2	Candidate is able to identify appropriate diagnostic method for detecting infectious diseases
PO3	Able to comprehend the Importance of Microorganism in Agriculture, Environment and attain competency to get placed in industry sectors
PO4	The student is able to understand the genetics of microbes and manipulate the genes in microbes, animal and plant systems for human welfare
PO5	The student is able to genetically modify the microorganism to suit the human needs
PO6	Know about the production/fermentation process of microorganisms and commercialization of the product in Industries

BHARATHIAR UNIVERSITY: COIMBATORE – 641 046
PG Diploma, INDUSTRIAL BIOTECHNOLOGY (UNIVERSITY)
FOR THE STUDENTS ADMITTED DURING THE ACADEMIC YEAR
2022 – 2023 BATCH & ONWARDS
SCHEME OF EXAMINATION

Semester/ Code No.	Paper	Subject	University examination			Credit
			Internal Mark	External Mark	Total Mark	
SEMESTER I						
23MBTAC01	Paper-I	Biochemistry and Biostatistics	25	75	100	5
23MBTAC02	Paper - II	Molecular Techniques	25	75	100	5
23MBTAC03	Paper - III	Molecular Diagnostics	25	75	100	5
23MBTAC04	Paper - IV	Experimental animal care	25	75	100	5
23MBTAC05	Paper – V	Cell Culture Techniques	25	75	100	5
23MBTAC06	Paper - VI	Fundamentals of Fermentation Technology	25	75	100	5
SEMESTER II						
23MBTAGE01	Elective	Industry Oriented Paper	50	50	100	5
		Industry Training*	250	250	500	25
		Grand total			1200	60

* The training will be carried out by the candidate in the industry and should be authenticated and countersigned by the Head of the Industry and HOD. This training will be reviewed by industry. Candidate who has presented the work as 'Not qualified as per CBCS' must resubmit the project again in the ensuing academic year

Industry Oriented Paper

Semester/ Code No.	Paper	Subject	University examination			Credit
			Internal Mark	External Mark	Total Mark	
23MBTAGE01	Elective	Good Manufacturing Practices	25	75	100	5

Course code	23MBTAC01	BIOCHEMISTRY AND BIOSTATISTICS	L	T	P	C
CorePaper			3	1	1	5
Pre-requisite		Basic knowledge on Biochemistry	Syllabus Version		2023-24	

CourseObjectives:

The main objectives of this course are to:
To impart knowledge on Buffers and Solutions
To understand the concepts in Biostaistics
To provide hands on experience in the concept

Expected Course Outcomes:

On the successful completion of the course, student will be able to:

1	Appreciate how biochemical pathways and processes are integrated into a network, which provides robustness to life.	K2
2	Analyze the role buffers in research experiment.	K4
3	Evaluate the type of statistical tools to be used.	K5
4	Can characterize the biomolecule of interest.	K5
5	Will have hands on experience on immunotechniques	K2

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

Unit:1 **10hours**

PH meter- pH scale, Henderson- Hassalbalch equation, Buffer solutions, Buffer systems of blood-Hb, Buffer systems. Various ways of expressing and conversion of concentration of solutions-molality, molarity, normality, mole fraction.

Practical:

a. Preparation of buffer and its pH measurements using pH meter.
b. Simple problems to be worked out (molality, molarity, normality, mole fraction).

Unit:2 **12hours**

Principles of chromatography, size exclusion, Ion-exchange and affinity chromatographies. High performance liquid chromatography (HPLC), Gas liquid chromatography (GLC), Thin layer chromatography (TLC), Paper chromatography, GC-MS, LC-MS, MaldiTof, ICPMS and Surface Plasma Resonance methods.

Spectroscopic techniques: Properties of electromagnetic radiation, interaction with matter. Gamma ray spectroscopy, X-ray spectroscopy, UV and Visible spectroscopy, Infrared and Raman spectroscopy, Electron spin resonance spectroscopy, Nuclear magnetic resonance spectroscopy, Circular dichorism spectroscopy, Atomic absorption spectroscopy. Lasers, Spectrofluorimetry, turbidometry and nephelometry.

Electrophoresis: General principles, Electrophoresis of proteins: SDS-PAGE, Native gels, Gradient gel, Isoelectric focusing, 2-D gel electrophoresis (2-D PAGE), cellulose acetate

electrophoresis, continuous flow electrophoresis; Detection, estimation and recovery of proteins. Immunoblotting. Electrophoresis of nucleic acids: agarose gel electrophoresis of DNA, Pulse field gel electrophoresis, electrophoresis of RNA, Capillary electrophoresis. DNA sequencing - Next generation sequencing (NGS)

Practical:

a. Separation of amino acids by TLC.
b. Analysis of proteins by LC-MS.
c. Separation of proteins by SDS-PAGE.
d. Detection and characterization of Proteins by Immunoblotting.
e. Separation of DNA by Agarose gel electrophoresis.

Unit:3		**12hours**

Immunology: Innate and acquired immunity, Antibody mediated and cell mediated response tolerance. Primary and secondary lymphoid organs. Structure of T, B and NK cells. Receptors on the surface of lymphocytes. Structure and functions of neutrophils, Macrophages – phagocytosis and inflammation, eosinophils and basophils.

Antigen: Properties, Specificity and Cross reactivity, antigenicity, immunogenicity, antigen determinants, Haptens, adjuvants, Self-antigens (MHC) an outline only.

Antibodies: Properties, classes and subclasses of immunoglobulin's: Structure, specificity and distribution, Clonal selection theory of antibody formation. Antigen-antibody interaction – Precipitation and agglutination – Definition and mechanism of formation. Complement component. Cytokines and their junctions.

Practical:

a. Immunodiffusion- Single radial and double diffusion.
b. Rocket immunoelectrophoresis.
c. ELISA- Direct and Indirect.
d. Isolation and purification of IgG from serum.

Unit:4		**10hours**

Organising a statistical survey - Planning and executing the survey. Source of data - Primary and secondary data, Collection - observation; interview; enquiry forms, questionnaire schedule and check list. Classification and tabulation of data. Diagrammatic &graphic presentation of data.

Measures of central tendency: arithmetic mean, median, mode, quartiles, deciles and percentiles. Measures of variation: range, quartile, deviation, mean deviation, standard deviation. Correlation analysis: Scatter diagram, Karl Pearson's coefficient of correlation and Spearman's rank method. Regression analysis.

Practical:

Case study – Submit a review of one research which has utilised this statistics.

Unit:5		8hours

Sampling distribution and test of significance: Testing of hypothesis errors in hypothesis testing, standard error and sampling distribution. Sampling of variables (large samples and small samples). Student's 't' distribution and its applications. Chi - square test &goodness of fit. Analysis of variance one-way and two-way classification, Duncan's MultipleRange Test. Design of experiment - completely randomized block design.

Practical:

Perform ANOVA and Student's 't' test for the given experiments.

Unit:6	AI in Biochemistry and statistics	4hours

https://www.youtube.com/watch?v=gVzPMZqOTo4
https://www.youtube.com/watch?v=Y74h6DQAlPY
https://www.youtube.com/watch?v=ey9eF7GX3BM
https://www.youtube.com/watch?v=j85wCqVitaM

E-learning **2hours**

https://onlinecourses.nptel.ac.in/noc20_cy10/preview
https://www.classcentral.com/course/swayam-biostatistics-and-mathematical-biology-13925
https://www.coursera.org/specializations/advanced-statistics-data-science

	Total Lecture hours	58hours

Text Book(s)

1	ChemistryofBiomolecules an Introduction, Richard J. Simmons, Royal Society of Chemistry,1992
2	

Reference Books

1	LehningerPrinciplesofBiochemistrybyAlbertL.Lehninger,DavidL.Nelson,MichaelM.Cox
2	

Related Online Contents [MOOC, SWAYAM, NPTEL, Websites etc.]

1	https://onlinecourses.swayam2.ac.in/cec19_bt02/preview
2	https://onlinecourses.swayam2.ac.in/cec20_bt12/preview
3	https://onlinecourses.nptel.ac.in/noc19_bt19/preview

Course Designed By: Dr. S. Suja and Dr. J. Angayarkanni						
Mapping with Programme Outcomes						
COs	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	S	L	S	L	M	M
CO2	M	L	S	L	S	L
CO3	S	L	L	L	S	L
CO4	M	L	L	L	M	L
CO5	L	L	M	M	L	L
CO6	L	L	L	L	M	L

Course code	23MBTAC02	**Molecular Techniques**	L	T	P	C
Core Paper			3	1	1	5
Pre-requisite	**A knowledge on biomolecules**		**Syllabus Version**	**2023-24**		

Course Objectives:

The main objectives of this course are to:
To learn molecular tools available
To understand usage of molecular techniques
To gain knowledge on vector construction and cloning

Expected Course Outcomes:

On the successful completion of the course, student will be able to:

1	Construct a vector of need	K6
2	Interpret sequence pattern	K4
3	Clone and transfer gene of interest	K4
4	Identify mutation	K5

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

Unit:1 **10hours**

Vector construction : Construction of vector for microbial transformation; construction of vector for plant transformation; construction of vector for cell line transformation

Practical 1:

1. Construct a vector (diagrammatic construct) for microbial host, plant host and cell line host

Unit:2 **12hours**

Cloning strategies – Vector mediated transfer, viral mediated transfer, Agrobacterium mediated transfer

Practical 2:

1. Perform calcium mediated transfer of gene
2. Perform Agrobacterium mediated transfer

Unit:3 **10hours**

Types of PCR - Real-Time PCR (quantitative PCR or qPCR), Reverse-Transcriptase (RT-PCR), Multiplex PCR, Nested PCR, High Fidelity PCR, Fast PCR, Hot Start PCR, GC-Rich PCR; **Library construction** - Construction of cDNA Library - use of phagemids and Cosmids; **Genome editing**: Double stranded DNA breakage - Homologous recombination - Non homologous recombination - site specific recombination - engineered nuclease - mega nucleases, Zinc finger nucleases, TALEN, MAGE – CRISPR; Base editing

Practical 3:

1. Perform RT PCR for a selected gene

Unit:4		**10hours**
DNA sequencing- DNA and RNA hybridization- Southern and Northern blotting - Sangers method - Basics of pyrosequencing, Next Generation Sequencing strategies - western blotting for proteins; **Application** in human genetics and forensic science - RAPD, RFLP, AFLP, SSCP, Dot and colony blotting **Practical 4:** 1. Perform RAPD for a sample 2. Western blotting 3. Interpret a NGS result of a sample		
Unit:5		**10hours**
DNA mutation diagnosis: allele specific oligonucleotides (ASO), protein truncation test, single strand conformational polymorphism (SSCP), Nucleotide sequencing, Denaturing gradient gel electrophoresis, heteroduplex analysis, DNA micro array analysis; Reversion - AMES Test **Practical 5**: 1. Perform SSCP		
Unit:6	**AI in Molecular techniques**	**6hours**
Expert lectures,online seminars–webinars		
Machine Learning in Genomics–Current Efforts and Future Applications Synthetic Biology, Artificial Intelligence and Quantum Computing DNA as digital storage tool		
E-learning		**2hours**
https://epgp.inflibnet.ac.in/Home/ViewSubject?catid=3 GeneticEngineering&rDNAtechnology–sitedirectedmutagenesisCloning strategies Moleculartherapeutics–geneediting,generegulationandgenesilencing https://epgp.inflibnet.ac.in/Home/ViewSubject?catid=2Molecular Biology, genetic engineering &Biotechnology–DNA repair;DNAdamage;Geneticrecombination		
	TotalLecturehours	**60hours**

TextBook(s)

1	Principles of Gene Manipulation and Genomics- S.B.Primrose and R.M.Twyman, John Wiley & Sons Ltd, 7th edition, 2006
2	Molecular Genetics: An introductory narrative, Second Edition - Gunther.S.Stent and Richard Calendar, 2002. CBS Publishers and distributors.
3	Gene cloning and DNA anlaysis, T.A. Brown, John Wiley & Sons, 2013
4	Genome editing in Animals: Methods and protocols, Ishuo hatada, Springer publications, 2017
5	Genome editing and engineering, Krishnarao Appasani and George M. Church, Cambridge University Press, 2018
6	Genome editing, Kursad Turksen, Springer publications, 2016

ReferenceBooks	
1	Microbial Genetics, Stanley R Maloy; John E Cronan; David Freifelder, Boston : Jones and Bartlett Publishers, second edition, ©1994.
2	A Short Course in Bacterial Genetics: A Laboratory Manual and Handbook for Escherichia coli and Related Bacteria- Jeffrey. H. Miller, 1992.CSHL Press
3	Genetics of microbes**,** Brian W. Bainbridge, **DOI**https://doi.org/10.1007/978-1-4615-7093-6
4	Plant genome editing with CRISPR systems: Methods and protocols,Yipping Qi, Humana press, 2019
5	Targeted genome editing using site-specific nucleases, Takashi Yamamoto, Springer publishers, 2015
6	Viral vectors for gene therapy; Methods and protocols, Fredric P. Manfredson, Mattew J. Benskey, Humana press
7	E.coli plasmid vectors: Methods and applications, Nicola Casali, Andrew Preston, Humana press
RelatedOnlineContents[MOOC,SWAYAM,NPTEL,Websitesetc.]	
1	https://swayam.gov.in/nd1_noc20_bt32/preview-Genetic engineering
2	Synthetic Biology, Artificial and Quantum Computing DOI: Intelligence,http://dx.doi.org/10.5772/intechopen.83434
3	Machine Learning in Genomics– Current Efforts and Future Applications https://emerj.com/ai-sector-overviews/machine-learning-in-genomics-applications/
4	DNA digital data storage https://geneticeducation.co.in/dna-digital-data-storage/; https://www.nature.com/articles/s41576-019-0125-3
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Course Designed By: Dr.J.Angayarkanni	

COs	PO1	PO2	PO3	PO4	PO5	PO6
CO1	L	S	L	L	L	L
CO2	M	S	L	L	L	L
CO3	L	L	L	L	L	L
CO4	L	L	L	L	L	L
CO5	L	L	L	M	L	L
C06	L	L	L	L	L	L

Course code	23MBTAC03	MOLECULAR DIAGNOSTICS	L	T	P	C
Core Paper			3	1	1	5
Pre-requisite		Basic knowledge molecular techniques	Syllabus Version		2023-24	

Course Objectives:

The main objectives of this course are to:
Impart knowledge on types of specimens
Understand methods of collection and processing of specimens

Expected Course Outcomes:

On the successful completion of the course, student will be able to:

1	Knowledge on type on specimens and their processing	K2
2	Isolate pathogens from specimens	K4
3	Diagnose pathogens from specimens through direct methods	K4
4	Handle highly infectious disease sample in accordance with GLP	K5

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

Unit:1	Sample collection and preparation	10hours

Clinical specimens: National and International guidelines for Sample collection- method of collection, transport and processing of samples, Personal safety and laboratory safety. GLP for handling highly infectious disease samples and documentation. Ethical issues related to molecular diagnostics.

Practical 1:

1. Collection of throat swab specimen
2. Isolation of pathogen from throat swab.

Unit:2	DNA Based Diagnosis	15hours

PCR based assays: Real-time PCR, ARMS, multiplex, methylation analysis, MLPA, competitive oligonucleotide priming, DHPLC, CSCE. Mutation screening panels (xTAG, Luminex) Micro arrays: SNP chromosomal microarrays, EST, SAGE, NGS in diagnostics

Practical 2

1. PCR based pathogen detection
2. NGS -DEMO

Unit:3	Proteomic and Metabolomics Assays for Diagnostics	10hours

Diagnostic proteomics: SELDI-TOF MS, Isotope coated affinity tag (ICAT), SILAC, i-TRAQ, Protein microarray. Metabolite profile for biomarker detection in the body fluids/tissues under various metabolic disorders.

Practical 3

1. Isolation of total protein from collected specimen
2. Detection of specific protein using LC-MS

Unit:4	Applications of Molecular Diagnostics	10hours

Major Histocompatibility Complex (MHC), HLA typing, RFLP, PCR based methods, SSO, SSP and SBT methods. Diagnosis of inherited diseases- Thalassemia, Cystic Fibrosis. Neonatal and Prenatal disease diagnostics Prenatal and pre-implantation diagnosis. Noninvasive: Triple test, Ultrasonography (USG), Invasive: Amniocentesis (AC), chorionic villi sampling. Molecular diagnosis for early detection of Down syndrome. Fragile X syndrome.

Practical 4: Lab visit for Ultrasonography and HLA typing

Unit:5	Applications In Molecular Oncology And Microbial Diseases	13hours

Molecular oncology testing in malignant disease- General methods for molecular diagnosis of cancer . Circulating tumour cell testing (CTC). Molecular diagnosis of various viral diseases: Dengue, SARS and COVID 19 comorbidities. Direct detection & identification of pathogenic-organisms - 16s rRNA typing. AI enabled multimodel diagnostics

Practical 5

1. Detection of comorbidities of bacterial infection through real time PCR

Unit:6	AI in Molecular Diagnostics	12hours

2. https://genomemedicine.biomedcentral.com/articles/10.1186/s13073-019-0689-8
3. https://aacrjournals.org/clincancerres/article/27/5_Supplement/IA-19/32789/Abstract-IA-19-Machine-learning-and-AI-in
4. https://www.labcompare.com/10-Featured-Articles/576229-The-AI-Technologies-Driving-Advancements-in-Clinical-Diagnostics/

E-learning **2hours**

https://onlinecourses.nptel.ac.in/noc20_cs42/preview

	Total Lecture hours	72hours

TextBook(s)

1	Wayne W. Grady, Robert M. Nakamura, Charles M Strom and Frederick L. Kiechle. Molecular Diagnostics: Techniques and Applications for the Clinical Laboratory. Academic Press
2	Pongali Raghavendra and Thammineni Pullaiah Advances in cell and molecular diagnosis. Academic Press
3	Geaorge P. Patrinos, Wilhem J. Ansorge and Philip B. Danielson Molecular Diagnostics. Maca Haley, Academic Press
4	David E. Bruns, Edward R. Ashwood and Carl A. Burtis. Fundamentals of Molecular Diagnostics. Saunders Elsivier.

ReferenceBooks

1	Nader Rifal, Andrea Rita Horvath, Carl T. Wittwer and Janson Y. Park. Principles and applications of molecular diagnostics. Elsevier

RelatedOnlineContents[MOOC,SWAYAM,NPTEL,Websitesetc.]

1	https://www.youtube.com/watch?v=LKkp457UnOY
2	https://www.youtube.com/watch?v=u0oTLNmXINE
3	https://www.youtube.com/watch?v=3NiFjm_SiFs

Course Designed By: Dr. K. N. Brahmadathan and Dr. V. Brindha Priyadarisini

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6
CO1	S	S	S	M	M	S
CO2	L	M	M	M	L	S
CO3	L	L	L	L	L	S
CO4	M	L	L	M	L	S

PAPER IV- EXPERIMENTAL ANIMAL CARE

UNIT-1

Regulations, guidelines, and animal models: Laws, Regulations, and Guidelines Governing Research Animal Care and Use in India- General Framework and principles, Regulatory authorizations and enforcement mechanisms, guidelines and considerations of various test animals-dog, nonhuman primates, equine, genetically altered animals, Oversight and ethical review, institutional and designated personnel, Experimental procedures and euthanasia, transportation, housing and enrichment, animal husbandary and environment.

Practical session: *Draft an experimentation protocol to evaluate the toxicity of a given drug using rodents*

UNIT 2

Basics in animal experimentation: General principles in animal housing- Handling, care and components of animal facility. Institutional Animal Care and Use Committee, Drafting of animal experimental protocol. Grouping of animals- positive and negative control. Dissection and identification of organ system, storage and transportation. Blood sample collection in small laboratory animals. Separation of plasma and serum. Principles of rodent surgery.

***Practical session*:** *Dissection of rat and mice to collect blood, identification and harvesting of organs, surgical techniques (Ovariectomy and orchidectomy).*

UNIT 3

Laboratory experiments related to animal research: Assays related to animal experiments: Body and organ weight measurement. Serum assays: Liver parameters- AST, ALT- Kidney parameters- Urea, uric acid, creatinine- Cholesterol, LDL, VLDL, HDL, triglycerides, antioxidants, histopathology, proteomic studies, gene expression studies.

Practical session: *Enzyme analysis (AST, ALT) and biochemical analysis (urea, uric acid, creatinine, total cholesterol, LDL, VLDL, HDL, triglycerides, antioxidants) using Autoanalyser, Histological processing of tissues (liver and kidney), Tissue sectioning using microtome, slide preparation and visualization under microscopy, and real-time interpretation.*

UNIT 4

Use of animals in research: Different strains of mice and rats-Antibody production- Rodents in disease research- Genetically engineered animal models- Behavioral testing of animals- Open field exploration test- elevated plus maze- Light-dark exploration test- Social interaction test.

Practical session: *Estrous cycle determination using vaginal smear, Behavioral analysis (choice test using Y-maze apparatus, forced swim test, tail suspension test, and Light-dark exploration test).*

UNIT 5

Alternative to animal research: Alternatives to animal research: Concept of "Alternatives"- A brief account of Agencies / Organizations - OECD, ECVAAM, and ICCVAM - List of validated alternative methods- Scenario in India-Alternatives in education models, mannequins, plastinated specimens, CAL and digital alternatives- *Danio rerio*- biology; model for environmental toxicity, reproductive toxicity, investigating endocrine disruption; *Hydra*- model for developmental biology, apoptosis studies. Molecular modeling and docking methods –tools/software; In silico approach to Pharmacokinetics and Pharmacodynamics

Practical session: *Use virtual dissection software and in silico tools (pharmacokinetics) to perform an experiment.*

References:

Quadri et al., 2018. Laws, Regulations, and Guidelines Governing Research Animal Care and Use in India, In: Laboratory Animals, Chapter 8, 2nd Edition, edited by Javier Guillen, Academic press. https://doi.org/10.1016/B978-0-12-849880-4.00008-8.

Course code	23MBTAC05	CELL CULTURE TECHNIQUES	L	T	P	C
Core Paper			3	1	1	5
Pre-requisite			Syllabus Version		2023-24	

Course Objectives:

The main objectives of this course are to:

- Understand the basic and latest techniques for in vitro cell culture of plants and animal.
- Providing advanced knowledge about use of plant biotechnology in breeding and micropropagation techniques.
- Introduce the students to the theory and practice of plant tissue culture and their role from modifying plants in plant biotechnology to the propagation of endangered plants
- The practical exposure would kindle the ideas of students to come up with novel applications of the field
- The technical details would expand the knowledge on the field that would equip the students to implement their views.
- Ability to understand the components of the tissue architecture

Expected Course Outcomes:

On the successful completion of the course, student will be able to:

1	Understand the types of plant tissue culture	K2
2	Gain knowledge on types of animal cell culture	K2
3	Culture plant cell	K6
4	Cultivate animal cell line	K6

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

Unit:1		**10hours**

Laboratory organization and Techniques in Plant Tissue Culture. Organ culture, root, shoot tip or meristem, ovary, flower and ovule culture and their importance. Callus culture-principle, protocol and significance, Cell suspension culture – Principle, protocol and its importance. Totipotency, cytodifferentiation and organogenesis – Principle, factors influencing Organogenesis and applications.

Practicals:

- Preparation of MS medium.
- Callus induction
- Suspension cell culture

Unit:2		**15hours**

Somatic embryogenesis and synthetic seeds – Principle, protocol and importance.Single cell culture, embryo culture – Principle, protocol and applications. Anther and Pollen culture – Principle, protocol, and its significance. Protoplast, isolation, fusion and culture somatic hybridization, chemofusion, electrofusion, important properties of protoplast, somatic hybrids, cybrids – Principle, protocol and importance.

Practicals:

- Synthetic seed preparation
- Protoplast isolation and fusion.

Unit:3		**10hours**
Somaclonal variation – Causes and significance, plant tissue culture in forestry, micro propagation, clonal propagation production of useful biochemicals – Gene conservation bank – plant tissue culture in biotechnology-commercial aspects of plant tissue culture. **Practicals:** • Micropropagation		
Unit:4	Applications of Molecular Diagnostics	**10hours**
Animal cell culture techniques: Introduction - Biology of cultured cells. Basic requirements for animal cell culture-Equipments and consumables. Animal cell culture media- Balanced salt solutions and simple growth medium, Serum and protein free defined media; Types of animal cell culture - primary and established culture; organ culture; tissue culture; three dimensional culture feeder layers; disaggregation of tissue and Sub culture; cell line propagation, cell separation; cell synchronization; cryopreservation. **Practical:** • Preparation of DMEM media • Culturing of primary cells • Disaggregation of cells and sub culturing • MTT assay • Live cell imaging		
Unit:5		**13hours**
Stem cells: Introduction, biology and classification-Unipotent, Pluripotent and Totipotent. Sources of stem cells-embryonic stem cells, embryonic germ cells and adult stem cells (Mesenchymal, Umbilical cord blood cells, Adipose tissue). Stem cells characterization-Genetic markers and membrane markers. **:** Therapeutic applications of stem cell **Tissue Engineering**: Principles, tissue engineering triad – Basic Constituents (Matrix molecules, Ligands, Growth factors, Biomaterials). Tissue engineering bioreactors. Biodegradable polymers in tissue engineering. Therapeutic applications of tissue engineering **Practical :** 3D print-visit		
Unit:6	**AI in cell culture**	**12hours**
Machinelearningsoftwareintoxicology:asteptowardlabanimalreductionhttps://www.biocompare.com/Editorial-Articles/351896-Realizing-New-Possibilities-for-Cell-Line-Optimization/https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0213626https://www.sciencedirect.com/science/article/pii/S2452310018300027https://jandeboerlab.com/research/computational-sciences/machine-learninghttps://www.nature.com/articles/s41598-019-50208-x		
E-learning		**2hours**
https://www.nature.com/articles/s41598-020-60278-xhttps://www.frontiersin.org/articles/10.3389/fpls.2016.00274/full https://nptel.ac.in/courses/102/103/102103016/https://ocw.mit.edu/courses/biology/7-013-introductory-biology-spring-2013/video-lectures/lecture-23-stem-cells/http://epgp.inflibnet.ac.in/Home/ViewSubject?catid=3 https://www.ptglab.com/support/cell-culture-protocol/introduction-to-cell-culture/		
	Total Lecture hours	**72hours**

TextBook(s)	
1	An introduction to genetic engineering in plants, Mantel, Mathews and Mickee, 1985. Blackwell Scientific Publishers. London.
2	Plant Biotechnology by Mantell, S.H and Smith, H. 1983. Cambridge University press, UK
3	Culture of Animal Cells: A Manual of Basic Technique and Specialized Applications, 6th Edition- R. Ian Freshney (Wiley Publishing)
4	Animal Cell Culture: A Practical Approach, 3rd Edition -John R. W. Masters (Oxford University Press)
5	Principles of Tissue Engineering, 4th Edition, Robert Lanza, Robert Langer, Joseph P. Vacanti.(Academic Press)
6	Principles of genetic manipulation; Ed. Old and Primrose, 6th Edition. Blackwell science publication.
ReferenceBooks	
1	Edwin F. George and Paul Sherington, D. 1984. Plant Propagation by Tissue Culture, Exegetics Ltd., Edington, Westbury, England.
2	Indra K. Vasil, 1980. Cell Culture and Somatic Cell Genetics of Plants. Academic Press Inc., New York.
3	Kalyanakumar De. 1997. An Introduction to Plant Tissue Culture, New Central Book Agency, Calcutta.
4	R.L.M. Pierik, 1987. In vitro culture in higher plants. Martinus Nijhoff Publishers, Boston.
5	Methods in cell biology; Volume 57, Animal cell culture methods, Ed. Jennie P. Mather, David Barnes, Academic press
6	Mammalian cell biotechnology; A practical approach, Ed. M. Butler, Oxford University press.
7	Stem Cells: Scientific Progress and Future Research Directions (http://stemcells.nih.gov/)
8	Essentials of Stem Cell Biology, 2nd Edition - Robert Lanza, John Gearhart, Brigid Hogan, Douglas Melton, Roger Pedersen, E. Donnall Thomas, James Thomson and Sir Ian Wilmut (Academic Press)
Related Online Contents [MOOC,SWAYAM,NPTEL,Websitesetc.]	
1	https://actascientific.com/ASAG/pdf/ASAG-02-0156.pdf
2	https://www.sciencedirect.com/science/article/pii/S2214317319300940
3	https://www.nature.com/articles/s41598-020-60278-x
4	https://www.frontiersin.org/articles/10.3389/fpls.2016.00274/full
Course Designed By Dr. G. Kapildev	

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6
CO1	S	S	S	M	M	S
CO2	L	M	M	M	L	S
CO3	L	L	L	L	L	S
CO4	M	L	L	M	L	S

Course code	23MBTAC06	Fundamentals of fermentation technology	L	T	P	C
CorePaper			3	1	-	4
Pre-requisite		Basic knowledge on fermentation process	Syllabus Version		2023-24	

Course Objectives:

The main objectives of this course are to:

1. Will provide technical information on fermenter designing and kinetics involved in the fermentation processes.
2. Aims to empower the students with various designs of fermenter.

Expected Course Outcomes:

On the successful completion of the course, student will be able to:

1	Gain wide information about types of fermentor	K2
2	Able to understand kinetics in fermentation	K2
3	Formulate condition required for the product of interest.	K6
4	Abletostartsmallscaleindustriesonspirullinaandmushroomcultivation.	K5

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

Unit:1		10hours

Types and design of bioreactor: Fermentor structure - Construction material, Basic components – Agitator, aerator, valves and steam traps, seals, stirrer glands. **Measurement and control of parameters** (on-line and off line sensors) – temperature, flow rate, pressure, pH, DO, gas analysis, computer control pathways. **Fermentors** - Air-lift, stirred tank, tower, fluidized bed, packed bed, pulsed, photo bioreactors, CSTR, PFR.

- Callus induction
- Suspension cell culture

Unit:2		15hours

Process kinetics: Kinetics - batch, fed-batch and continuous process; Sterilization methods - batch sterilization, continuous sterilization of medium. and air. Solid state and submerged; aerobic and anaerobic fermentation. **Inoculum development –** Development of inocula for yeast, bacterial, mycelial and vegetative fungal processes; aseptic inoculation of the fermentor. **Mixed microbial populations**; **Immobilization** - immobilization of cells and coimmobilizatio **Chemical kinetics** and classification of chemical reactors. **Transport phenomena** - Mass transfer, heat transfer, oxygen transfer; transfers in immobilized cells.

Unit:3		10hours

Production kinetics: Design for single and multiple reaction**:** size comparisons of single reactor for single reactions, multiple reactor systems for single reaction, reactions in parallel, in series, and series-parallel reactions of first order. Heterogeneous reactions - kinetics and mechanism of heterogeneous, non catalytic, and catalytic reactions; Non ideal flow - residence time distribution studies, C,E, F and I curves; RTD in ideal reactors; Models for Non ideal flow – zero –parameter model, One parameter model and two parameter model

Unit:4	Applications of Molecular Diagnostics	**10hours**
Downstream processing: Removal of microbial cells and solid matter, foam separation, precipitation, filtration, centrifugation, cell disruptions, liquid-liquid extraction, chromatography, membrane process, drying and crystallization		
Unit:5		**13hours**
Quality analysis: Quality analysis and product formulation - Product appearance, product stabilization and shelf life analysis, usage specific formulations, quality analysis and control. Fermentation economics of citric acid – process economics and project economics.		
Unit:6	**AI in Fermentation Technology**	**12hours**
Applications of Artificial Intelligence In Bio-Industry–Clinical Trials, Big Data Processing, Machine Learning & Automation. Industry video tours, Seminars/Webinars, Expert lectures		
E-learning		**2hours**
SWAYAM-https://www.classcentral.com/course/swayam-principles-of-downstream-techniques-in-bioprocess-3967 NPTEL-https://nptel.ac.in/courses/102/105/102105064/#AspectsofBiochemicalEngineering, Prof.DebabrataDas,IITKharagpur NPTEL - https://nptel.ac.in/courses/102/106/102106083/TransportPhenomena in Biological Systems-Prof.Suraish kumar, IITMadras		
	Total Lecture hours	**72hours**

TextBook(s)	
1	Fundamentals of Bioanalytical Techniques and Instrumentation, Ghosal and Srivastava, PHI Learning Pvt. Ltd., 2009.
2	. Principles of Fermentation technology, Stanbury PF and Whitaker A. Pergamon Press, 1984.
3	Introduction to Biochemical Engineering, D.G.Rao, Tata McGraw Hill Publishers, 2005.
4	Bioprocess Engineering: Basic Concepts, 2nd edition, Shuler,M.L. and Kargi, F., Prentice Hall, Engelwood Cliffs, 2001
5	
6	
Reference Books	
1	. Instrumentation, measurement and analysis, II edition, Nakra BC and Chaudhry KK, Tata McGrawHill Publishing Co. Ltd., New Delhi, 2004
2	Fermentation Microbiology and Biotechnology , Mansi El-Mansi and Charlie Bryce, Taylor and Francis Ltd., 2002
3	Manual of Industrial Microbiology and Biotechnology, III edition, Arnold L. Demain and Julian Davies, ASM press, Washington DC, 1999.
4	Biochemical Engineering Fundamentals, Baily,J., Bailey J. and Ollis,D.F., McGraw-Hill Book Co. New York, 1986.

5	. Pharmaceutical Biotechnology: Fundamentals and Applications, 3rd edition, Daan J. A. Crommelin, Robert D. Sindelar, and , Bernd Meibohm, 2007.
6	Handbook of Downstream processing, Edin Goldberg, Blackie and Academic Professional, 1997.

RelatedOnlineContents[MOOC,SWAYAM,NPTEL,Websitesetc.]	
1	SWAYAM-https://www.classcentral.com/course/swayam-principles-of-downstream-techniques-in-bioprocess-3967
2	NPTEL-https://nptel.ac.in/courses/102/105/102105064/#AspectsofBiochemicalEngineering,Prof.DebabrataDas,IITKharagpur
3	NPTEL - https://nptel.ac.in/courses/102/106/102106083/TransportPhenomena_in_BiologicalSystems-Prof.Suraish kumar, IITMadras
Course Designed By Dr. Sivakumar and Dr. M. Gnanadesigan	

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6
CO1	S	S	S	M	M	S
CO2	L	M	M	M	L	S
CO3	L	L	L	L	L	S
CO4	M	L	L	M	L	S

Course code	23MBTAGE01	GOOD MANUFACTURING PRACTICES AND QUALITY ASSURANCE	L	T	P	C
Elective Paper			4	1	-	5
Pre-requisite		Basic knowledge on practices in bioprocess industry	Syllabus Version		2023-24	

Course Objectives:

The main objectives of this course are to:
Provide the student with an understanding of the principles and practice of GMP
Enable them to realize the importance and compliance of GMP.
Impart expertise on the Administrative structure in the Industries
Understanding about the designing an Industry and construction of SOPs
Learning on Artificial Intelligence role in Industry4.0

Expected Course Outcomes:

On the successful completion of the course, student will be able to:

1	Design the rules and regulation to be followed in an Industry	K3
2	Prepare SOPs for a product in an Industry	K6
3	Perform quality check for the raw materials and products	K4
4	Systematize the arrangement of equipment in the Industry	K5

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

Unit:1	Principles and Importance of GMP, Public Health Protection and Premises	9--hours

Principles and Importance of GMP – Definition of GMP, Quality management, Personnel, Risk management, Quality control, Documentation, Inspections, GDP, GLP.

Public Health Protection

- adulteration definition - approved chemicals (lubricants, steam additives, etc.) - toxic chemical control and storage - hazard review: chemical, physical, biological - potential sources (humans, animals, environment) and controls

Premises - Design, construction, and maintenance of the production and staff areas in the facility, Layout(design) of the facility-separation from farm/animals/pets(smallscale)-perimeter, entrances, drainage - construction, heating/ventilation, humidity control- separation raw versus pasteurize; product flow-equipment/pipelayout/drainage-water source(treatment, hardness) monitoring

Unit:2	Equipment and Personnel Management	8--hours

Equipment-Design, construction and maintenance of equipment, Equipment arrangement and operation, cleaning-in-place process.

Personnel- Ensuring facility personnel are qualified for their job responsibilities, personal health and disease control, personal hygiene; clothing, habits, hand wash, restrooms, plant traffic control.

Unit:3	Sanitation	8--hours

Sanitation-Sanitation programs: Cleaning and sanitation compounds and their uses–for process equipments-for environmental cleaning (drains,coolers,etc.)- influence of water quality, Formulation control-concentrations and time. Environment sanitation and monitoring-environmental monitoring/pathogen testing- pest control programs

Unit:4	Raw Material Testing, Good practices in production and control and Process Control	12--hours

RawMaterialTesting-Testing raw materials-Identifying when product or raw materials must be tested - Accepting raw materials from a vendor without additional regular testing- Supplier certification. Good practices in production and control-Controlling the manufacturing process
- Stages in the production cycle – contracting quality tools – R & D - Self-inspection programs forfabricators, packagers/labelers - Testing requirements for packaging materials including supplier

certification.
Finished Product Testing-Finished product testing-Writing product specifications
- Conditions and options for finished product testing, distributors-product storage-packaging, distribution. Process Control-refrigeration (potential hazardous compounds), pasteurization-culture, pH, incubation temperature, aging temperature.

Unit:5	**Quality Control Department and Audits**	**15--hours**

Quality Control Department and Audits - Establishing a QC department - Investigating productquality.Audits-Records-Maintainingaccurate,clear,andprecisedocuments-Identifyingindividuals responsible for maintaining documents. Validation -- Definition – PQ, DQ, OQ, IQQualification, Process validation, Cleaning validation and Computer validation. GMP regulations - US-FDA, Europe, Japan, ICH, PICS/S,WHO

Unit:6	**Contemporary Issues**	**2hours**

Expert lectures, online seminars–webinars

AI/ML in Warehouse Logistics
Machine Learning in Load forecasting and vehicle scheduling
ML in Supply chain Management
AI in Supplier Management

	Total Lecture hours	**54hours**

Text Book(s)

1	Compendium of Good Practices in Biotechnology,BIOTOLseries

ReferenceBooks

1	.AWHOguidetogoodmanufacturingpractice(GMP)requirements:Volume1,2,3,4,5.Part 2-Validation,byGillianChaloner-Larsson,Ph.D,GCLBioconsult,Ottawa
2	GoodManufacturingPracticesforPharmaceuticals,SixthEditionby:GrahamBunnPublisher:Informa Healthcare;6edition|424pages(2007)http://ebookee.org/Good-Manufacturing-Practices-for-Pharmaceuticals-Sixth-Edition_859976.html#uPYoXd8huFeqqXB9.99
3.	APrimer–GoodLaboratoryPrcaticesandcurrentmanufacturingpractice,byLudwigHuber, Published by Agilent Technologies, Germany (2002)http://www.chem.agilent.com/Library/primers/Public/59886197.pdf.
4.	GMP manual: Good manufacturing practices and implementation, http://www.gmp-publishing.com/media/ebooks/flyer/files/gmpmanual_eu_4c_online.pdf.

Related Online Contents [MOOC,SWAYAM,NPTEL,Websitesetc.]

1	InspectionandQualityControlinManufacturing-https://swayam.gov.in/nd1_noc20_me27/preview
2	ProductdesignandManufacturing-https://swayam.gov.in/nd1_noc20_me12/preview
3	Designforqualitymanufacturingandassembly-https://swayam.gov.in/nd1_noc19_me48/preview
4.	QualityDesignandControl-https://swayam.gov.in/nd1_noc20_mg18/preview

Course Designed By: Dr. Prem Kumar and Dr. V. Brindha Priyadarisini

Mapping with Programme Outcomes

COs	PO1	PO2	PO3	PO4	PO5	PO6
CO1	L	L	L	S	L	L
CO2	L	L	L	S	L	L
CO3	L	S	L	S	L	S
CO4	L	L	L	S	L	L