**SCHOOL OF BIOTECHNOLOGY & GENETIC ENGINEERING**

**DEPARTMENT OF MICROBIAL BIOTECHNOLOGY**

Syllabus

PG Diploma, Industrial Biotechnology (CBCS –UD)

2024-2025 BATCH & ONWARDS



**Bharathiar University: Coimbatore-641 046**

**(A State University, Accredited with “A++” Grade by NAAC and**

**21th Rank among Indian Universities by MHRD-NIRF)**

**Coimbatore 641 046, INDIA**

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| **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 |

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| **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 |

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| **Program Outcomes(POs)** | |
| *On successful completion of the PG Diploma in Industrial Biotechnology program the candidate will be able to* | |
| PO1 | Understand the Biochemical interactions in the living system |
| PO2 | Identify appropriate diagnostic method for detecting infectious diseases |
| PO3 | Design animal studies for validation of research finding |
| PO4 | Understand the concept of genetic engineering and manipulate the genes in microbes, animal and plant systems for human welfare |
| PO5 | Perform and apply cell culture experiments of both animal and plant tissues for human welfare |
| PO6 | Know about the production/fermentation process of microorganisms and commercialization of the product in Industries |
| PO7 | Acquire competency to work in the Industries related to life sciences |

**BHARATHIAR UNIVERSITY: COIMBATORE – 641 046**

**PG Diploma, INDUSTRIAL BIOTECHNOLOGY (UNIVERSITY)**

FOR THE STUDENTS ADMITTED DURING THE ACADEMIC YEAR

2024 – 2025 BATCH & ONWARDS

**SCHEME OF EXAMINATION**

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| --- | --- | --- | --- | --- | --- | --- |
| **Semester/**  **Code No.** | **Paper** | **Subject** | **University examination** | | | **Credit** |
| **Internal Mark** | **External Mark** | **Total Mark** |
| **SEMESTER I** |  |  |  |  |  |  |
| 24MBTAC01 | Paper-I | Biochemistry and Biostatistics | 25 | 75 | 100 | 5 |
| 24MBTAC02 | Paper - II | Molecular Techniques | 25 | 75 | 100 | 5 |
| 24MBTAC03 | Paper - III | Molecular Diagnostics | 25 | 75 | 100 | 5 |
| 24MBTAC04 | Paper - IV | Experimental animal care | 25 | 75 | 100 | 5 |
| 24MBTAC05 | Paper – V | Cell Culture Techniques | 25 | 75 | 100 | 5 |
| 24MBTAC06 | Paper - VI | Fundamentals of Fermentation Technology | 25 | 75 | 100 | 5 |
| **SEMESTER II** |  |  |  |  |  |  |
| 24MBTAGE01 | Elective | Industry Oriented Paper | 25 | 75 | 100 | 5 |
|  |  | Industry Training\* | 125 | 375 | 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**

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| **Semester/**  **Code No.** | **Paper** | **Subject** | **University examination** | | | **Credit** |
| **Internal Mark** | **External Mark** | **Total Mark** |
| 24MBTAGE01 | Elective | Good Manufacturing Practices | 25 | 75 | 100 | 5 |

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| **Course code** | | | | | | **24MBTAC01** | | **BIOCHEMISTRY AND BIOSTATISTICS** | | | | | L | | | P | | T | | C |
| **Core Paper** | | | | | | | | 3 | | | 1 | | 1 | | 5 |
| **Pre-requisite** | | | | | | | | **Basic knowledge on Biochemistry** | | | | | **Syllabus Version** | | | | | | | **2024-25** |
| **Course Objectives:** | | | | | | | | | | | | | | | | | | | | |
| 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 chromatograpic and spectroscopic methods in research experiment. | | | | | | | | | | | | | | | | | | K4 | |
| 3 | Will have hands on experience on immunotechniques | | | | | | | | | | | | | | | | | | K5 | |
| 4 | Can organize a statistical survey | | | | | | | | | | | | | | | | | | K5 | |
| 5 | Evaluate the type of statistical tools to be used. | | | | | | | | | | | | | | | | | | K2 | |
| **K1**-Remember;**K2**-Understand;**K3**-Apply;**K4**-Analyze;**K5**-Evaluate;**K6**–Create | | | | | | | | | | | | | | | | | | | | |
| **Unit:1** | | **ANALYTICAL METHODS** | | | | | | | | | | | | | **10 hours** | | | | | |
| 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.  **Enzyme kinetics**: Enzyme activity, specific activity, Determination of Km, Vmax using Eadie-Hofstee plot and Lineweaver-Burk plot; Inhibition activity – competitive and non-competitive  **Practical:**   1. Preparation of buffer and its pH measurements using pH meter. 2. Simple problems to be worked out (molality, molarity, normality, mole fraction). 3. Estimation of protein 4. Estimation of enzymes (substrate based and product based) | | | | | | | | | | | | | | | | | | | | |
| Unit:2 | | | | **CHROMATOGRAPHY AND ELECTROPHORETIC TECHNIQUES** | | | | | | | | | | 12 hours | | | | | | |
| Affinity column chromatography – Nickel column; High performance liquid chromatography (HPLC), Thin layer chromatography (TLC), Paper chromatography, GC-MS, LC-MS, MaldiTof, ICPMS and Surface Plasma Resonance methods.  **Spectroscopic techniques:** UV and Visible spectroscopy, Infrared and Raman spectroscopy, Electron spin resonance spectroscopy, Nuclear magnetic resonance spectroscopy, Circular dichorism spectroscopy, Atomic absorption spectroscopy.  **Electrophoresis:** Electrophoresis of proteins: SDS-PAGE, Native gels, Gradient gel, Isoelectric focusing, 2-D gel electrophoresis (2-D PAGE).  **Practical:**   1. Separation of amino acids by TLC. 2. Analysis of proteins by LC-MS. 3. Separation of proteins by SDS-PAGE. 4. Detection and characterization of Proteins by Immunoblotting. | | | | | | | | | | | | | | | | | | | | |
| **Unit:3** | | | | **IMMUNOTECHNIQUES** | | | | | | | | | | 12 hours | | | | | | |
| **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 immunoglobulins: 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:**   1. Immunodiffusion- Single radial and double diffusion. 2. Rocket immunoelectrophoresis. 3. ELISA- Direct and Indirect. 4. Isolation and purification of IgG from serum. | | | | | | | | | | | | | | | | | | | | |
| **Unit:4** | | | | **BASIC STATISTICS** | | | | | | | | | | **10 hours** | | | | | | |
| 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.  **Descriptive Statistics:** Measures of central tendency and Dispersion, Coefficient of Variation. Correlation and Regression analysis: Scatter diagram, Karl Pearson's coefficient of correlation and Spearman's rank method. Simple linear regression analysis – Problems.  **Practical:**  Case study – Submit a review of one research which has utilised this statistics. | | | | | | | | | | | | | | | | | | | | |
| **Unit:5** | | | | **BIOSTATISTICS** | | | | | | | | | | 8 hours | | | | | | |
| **Testing of hypothesis:** errors in hypothesis testing, standard error and sampling distribution. Large samples tests and small samples tests and its applications. Chi - square test &goodness of fit. Design of experiment - Completely Randomized Design (CRD), Randomized Block Design (RBD) and Latin Square design (LSD). Missing plot techniques – Problems.  **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> | | | | | | | | | | | | | |  | | | | | | |
| **Unit:6** | | | **AI in Biochemistry and statistics** | | | | | | | | | | | **2hours** | | | | | | |
|  | | | **E-learning** | | | | | | | | | | |  | | | | | | |
| <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** | | | | | | | | | | | | | | **58 hours** | | | | | | |
| **Text Book(s)** | | | | | | | | | | | | | | | | | | | | |
| Chemistry of Biomolecular an Introduction, Richard J. Simmons, Royal Society of  Chemistry,1992 | | | | | | | | | | | | | | | | | | | | |
| **Reference Books** | | | | | | | | | | | | | | | | | | | | |
| LehningerPrinciplesofBiochemistrybyAlbertL.Lehninger,DavidL.Nelson,MichaelM.Cox | | | | | | | | | | | | | | | | | | | | |
| **Related Online Contents [MOOC, SWAYAM, NPTEL, Websites etc.]** | | | | | | | | | | | | | | | | | | | | |
| <https://onlinecourses.swayam2.ac.in/cec19_bt02/preview>  <https://onlinecourses.swayam2.ac.in/cec20_bt12/preview>  <https://onlinecourses.nptel.ac.in/noc19_bt19/preview> | | | | | | | | | | | | | | | | | | | | |
| Course Designed By: **Dr. S. SUJA** and **Dr. J. ANGAYARKANNI** | | | | | | | | | | | | | | | | | | | | |
| **COs** | | | | | **PO1** | | **PO2** | | **PO3** | **PO4** | **PO5** | **PO6** | | | | | **PO7** | | | |
| **CO1** | | | | | S | | L | | L | L | L | L | | | | | M | | | |
| **CO2** | | | | | L | | L | | L | L | L | L | | | | | M | | | |
| **CO3** | | | | | L | | M | | L | L | L | L | | | | | M | | | |
| **CO4** | | | | | L | | L | | L | L | L | L | | | | | L | | | |
| **CO5** | | | | | L | | L | | M | L | L | L | | | | | L | | | |

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| **Course**  **code** | | | | | **24MBTAC02** | | **MOLECULAR TECHNIQUES** | | | | | **L** | | | **T** | | **P** | | **C** |
| **Core Paper** | | | | | | | **3** | | | **1** | | **1** | | **5** |
| **Pre-requisite** | | | | | | | **A knowledge on Biomolecular** | | | | | **Syllabus**  **Version** | | | | | | | **2024-**  **25** |
| **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 ableto: | | | | | | | | | | | | | | | | | | | |
| 1 | Determine the vector required for cloning experiments | | | | | | | | | | | | | | | | | K6 | |
| 2 | Strategize cloning experiment for specific expression studies | | | | | | | | | | | | | | | | | K4 | |
| 3 | Understand the application of PCR in various fields | | | | | | | | | | | | | | | | | K4 | |
| 4 | Understand the process of DNA sequencing and editing | | | | | | | | | | | | | | | | | K5 | |
| 5 | Acquire experimental skills | | | | | | | | | | | | | | | | | K5 | |
| **K1**-Remember;**K2**-Understand;**K3**-Apply;**K4**-Analyze;**K5**-Evaluate;**K6**-Create | | | | | | | | | | | | | | | | | | | |
| **Unit:1** | | | **VECTOR CONSTRUCTION** | | | | | | | | | | | **12hours** | | | | | |
| Types of Vector (Plasmids, Viral vectors, Cosmids and Artificial Chromosomes), Types of Transformation techniques (Transformation, Transduction & Transfection) used in Prokaryotic and Eukaryotic system.  Practical 1:   1. Construct a vector (diagrammatic construct) for Prokaryotic and Eukaryotic host | | | | | | | | | | | | | | | | | | | |
| **Unit:2** | | | **GENE CLONING** | | | | | | | | | | **10hours** | | | | | | |
| Gene Cloning– Principles of Gene Cloning, Preparation of Competent cells and its different methods (Calcium, PEG), Application of cloning in Agriculture and pharmaceutical industry with examples.  Practical 2:  1. Perform calcium-mediated transfer of gene | | | | | | | | | | | | | | | | | | | |
| **Unit:3** | | | **PCR** | | | | | | | | | | **14hours** | | | | | | |
| Types of PCR - Multiplex PCR, Nested PCR, Real-Time PCR (quantitative PCR or qPCR), Reverse-Transcriptase (RT-PCR) - cDNA Library.  Genome editing-Double stranded DNA breakage: Homologous recombination – Non- homologous recombination - site specific recombination. Engineered nuclease: mega nucleases, Zinc finger nucleases, TALEN, MAGE – CRISPR  Practical 3:  1. Perform RT PCR for a selected gene | | | | | | | | | | | | | | | | | | | |
| **Unit:4** | | | **DNA SEQUENCING** | | | | | | | | | | **12hours** | | | | | | |
| First Generation -Sanger and Next generation Sequencing -PyrosequencingNanopore - Whole Genome Sequencing  Blotting Techniques: Southern, Northern blotting and western blotting  Practical 4:  1. Sanger sequencing  2. Western blotting | | | | | | | | | | | | | | | | | | | |
| **Unit:5** | | | **MOLECULAR MARKERS** | | | | | | | | | | **12hours** | | | | | | |
| Molecular Marker Techniques-RAPD, RFLP, AFLP, SSCP, SSR, SNP and ESTs  Cytogenetic Techniques-FISH and GISH  Practical 5:   1. Perform a RAPD Analysis 2. Cytogenetic technique- FISH | | | | | | | | | | | | | | | | | | | |
| **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; DNA damage; Geneticre combination | | | | | | | | | | | | | | | | | | | |
| **Total Lecture hours** | | | | | | | | | | | | | **60hours** | | | | | | |
| **Text Book(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, I shuohatada, 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 | | | | | | | | | | | | | | | | | | | |
| **Reference Books** | | | | | | | | | | | | | | | | | | | |
| Microbial Genetics, [Stanley R Maloy](https://www.worldcat.org/search?q=au%3AMaloy%2C+Stanley+R.&qt=hot_author); [John E Cronan](https://www.worldcat.org/search?q=au%3ACronan%2C+John+E.&qt=hot_author); [David Freifelder](https://www.worldcat.org/search?q=au%3AFreifelder%2C+David.&qt=hot_author), Boston : Jones and Bartlett Publishers, second edition, ©1994. | | | | | | | | | | | | | | | | | | | |
| **Mapping with Programme Outcomes** | | | | | | | | | | | | | | | | | | | |
| Course Designed By: **Dr. J. Angayarkanni** | | | | | | | | | | | | | | | | | | | |
| **COs** | | | | **PO1** | | **PO2** | | **PO3** | **PO4** | **PO5** | **PO6** | | | | | **PO7** | | | |
| **CO1** | | | | L | | L | | L | S | M | L | | | | | M | | | |
| **CO2** | | | | L | | L | | L | S | L | L | | | | | M | | | |
| **CO3** | | | | L | | L | | L | M | L | L | | | | | M | | | |
| **CO4** | | | | L | | L | | L | S | L | L | | | | | M | | | |
| **CO5** | | | | L | | L | | L | S | L | L | | | | | L | | | |

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| **Course code** | | | | **24MBTAC03** | | | | | | **MOLECULAR DIAGNOSTICS** | | | | | | **L** | | | | | **T** | | **P** | **C** |
| **Core Paper** | | | | | | | | | | **3** | | | | | **1** | | **1** | **5** |
| **Pre-requisite** | | | | | | | | | | **Basic knowledge molecular techniques** | | | | | | **SyllabusVersion** | | | | | | | **2024-**  **25** | |
| **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 | | | Acquire knowledge on type on specimens and their processing | | | | | | | | | | | | | | | | | | | K2 | | |
| 2 | | | Diagnose pathogens from specimens through direct methods | | | | | | | | | | | | | | | | | | | K4 | | |
| 3 | | | Comprehend the complexity of proteome and metobolome | | | | | | | | | | | | | | | | | | | K4 | | |
| 4 | | | Understand the genetic disposition of inherited diseases | | | | | | | | | | | | | | | | | | | K5 | | |
| 5 | | | Acquire knowledge on molecular diagnostic techniques | | | | | | | | | | | | | | | | | | | K3 | | |
| **K1**-Remember;**K2**-Understand;**K3**-Apply;**K4**-Analyze;**K5**-Evaluate;**K6**–Create | | | | | | | | | | | | | | | | | | | | | | | | |
| **Unit:1** | | | | | | | | **CLINICAL SPECIMEN 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: ARMS, 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, 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: 1. 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** | | | | | | | | | | | |
| 1. <https://genomemedicine.biomedcentral.com/articles/10.1186/s13073-019-0689-8> 2. <https://aacrjournals.org/clincancerres/article/27/5_Supplement/IA-19/32789/Abstract-IA-19-Machine-learning-and-AI-in> 3. <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 | PongaliRaghavendra and ThammineniPullaiah 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. BrindhaPriyadarisini | | | | | | | | | | | | | | | | | | | | | | | | |
| **Mapping with Programme Outcomes** | | | | | | | | | | | | | | | | | | | | | | | | |
| **COs** | | | | | **PO1** | | | | **PO2** | | **PO3** | **PO4** | | **PO5** | **PO6** | | | | | **PO7** | | | | |
| **CO1** | | | | | L | | | | S | | L | L | | L | L | | | | | M | | | | |
| **CO2** | | | | | L | | | | S | | L | L | | L | L | | | | | L | | | | |
| **CO3** | | | | | L | | | | S | | L | L | | L | L | | | | | L | | | | |
| **CO4** | | | | | L | | | | S | | L | L | | L | L | | | | | L | | | | |
| **CO5** | | | | | L | | | | S | | L | L | | L | L | | | | | M | | | | |

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| **Course code** | | **24MBTAC04** | | **EXPERIMENTAL ANIMAL CARE** | | | **L** | **T** | **P** | **C** |
| **Core Paper** | | | | **3** | **1** | **1** | **5** |
| **Pre-requisite** | | | | **Basic knowledge on Biochemistry** | | | **Syllabus Version** | | | **2024-25** |
| **Course Objectives:** | | | | | | | | | | |
| The main objectives of this course are:  To impart knowledge on rules and regulations govern the experimentation on laboratory animals.  To understand the concepts in designing a protocol for animal experimentation.  To provide hands on experience in the various methods adopted in *in vivo* experimentation on rodents and their handling.  To provide knowledge on the alternative models available to minimize the use of laboratory animals. | | | | | | | | | | |
| **Expected Course Outcomes:** | | | | | | | | | | |
| On the successful completion of the course, student will be able to: | | | | | | | | | | |
| 1 | Remember the various committees and laws involved in experimentation on laboratory animals. | | | | | | | | | K1&K2 |
| 2 | Frame their own protocol to study *in vivo*experimentation on appropriate animal models | | | | | | | | | K6 |
| 3 | Perform animal handling and various procedures like estrus cycle determination, blood collection, dissection, surgery etc., | | | | | | | | | K3 |
| 4 | Achieve various biochemical and pathological analysis to determine the effect of a particular drug | | | | | | | | | K5 |
| 5 | Execute *in silico* models to study the effect of a drug and thereby reducing the usage of laboratory animals | | | | | | | | | K3 &K4 |
| **K1**-Remember;**K2**-Understand;**K3**-Apply;**K4**-Analyze;**K5**-Evaluate;**K6**–Create | | | | | | | | | | |
| **Unit:1** | | | **GUIDELINES & REGULATIONS** | | | | | | | **10hours** |
| 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 husbandry and environment.  **Practical session**: Draft an experimentation protocol to evaluate the toxicity of a given drug using rodents | | | | | | | | | | |
| **Unit:2** | | | **BASICS IN ANIMAL EXPERIMENTATION** | | | | | | | **12hours** |
| General principles in animal housing- Handling, care and components of animal facility.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** | | | **BIOCHEMICAL ASSAYS** | | | | | | | **12hours** |
| 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) using Autoanalyzer, Histological processing of tissues (liver and kidney), Tissue sectioning using microtome, slide preparation and visualization under microscopy, and real-time interpretation | | | | | | | | | | |
| **Unit:4** | | | **ANIMAL MODELS** | | | | | | | **9 hours** |
| **Use of animals in research:** Commonly used strains of mice and rats in research. Production of antibodies in laboratory animals. Rodents in disease research-CVD and Cancer. Genetically engineered animal models – knock-in & knock-out technologies. Behavioural testing in animals -Open field exploration test-elevated plus maze – Light-dark exploration test – Social-interaction test.  ***Practical session:*** Estrous cycle determination using vaginal smear. Behavioural analysis (Choice test using Y-maze apparatus, forced swim test, tail suspension test and Light-dark exploration test) | | | | | | | | | | |
| **Unit:5** | | | **ALTERNATIVES TO ANIMAL RESEARCH** | | | | | | | **9 hours** |
| 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- Daniorerio- 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 | | | | | | | | | | |
| **Unit:6** | | | **AI IN ANIMAL HANDLING** | | | | | | | **4hours** |
| <https://www.youtube.com/watch?v=HYjOA8e95Vk>  <https://avidialabs.com/dissection/>  <https://www.youtube.com/watch?v=u_bJ75DkRG0> | | | | | | | | | | |
| **E-learning** | | | | | | | | | | **2 hours** |
| 1. <https://www.youtube.com/@MazeEngineers/videos> 2. <https://www.kenhub.com/en/library/anatomy/liver-histology> 3. <https://youtu.be/p6CvQtGcI84?si=ydFOsnBmZWX_XJZ5> 4. <https://youtu.be/mAJXBi0iSJw?si=Tl6rJEInv4j1IBxE> 5. <https://youtu.be/Nl6_JZdLyro?si=mJB-JVGGupXqFqbV> 6. <https://youtu.be/ff9-BvzNHDY?si=Thwv5E7BqEfqmntA> 7. <https://www.youtube.com/watch?v=Dj7pet35GL0> 8. <https://www.youtube.com/watch?v=JD1Ibht-acU> 9. <https://www.youtube.com/watch?v=m6Wa4IT57sw> | | | | | | | | | | |
| **Total Lecture hours** | | | | | | | | | | **58hours** |
| **Text Book(s)** | | | | | | | | | | |
| 1 | AmbikaShanmugam’s Fundamentals of Biochemistry for Medical Students (2016), 8th Edition, edited by K.Ramadevi. Published byWolterskluwerindiaPvt Ltd. ISBN 9351296822, 9789351296829 | | | | | | | | | |
| 2 | Clinical Biochemistry: An Illustrated Colour Text(fifth) Edition (2013) by Gaw, Allan, Rajeev Srivastava ,Murphy Edin published by Churchill Livingstone | | | | | | | | | |
| **Reference Books** | | | | | | | | | | |
| 1 | Quadrietal., 2018. Laws, Regulations, and Guidelines Governing Research Animal Care and  Use in India, In: Laboratory Animals, Chapter 8, 2 nd Edition, edited by Javier Guillen,  Academic press. https://doi.org/10.1016/B978-0-12-849880-4.00008-8. | | | | | | | | | |
| 2 | Essentials of Laboratory Animal Science: Principles and Practices (2021), edited by P. Nagarajan, Ramachandra Gudde, Ramesh Srinivasan. Springer publication. ISBN 978-981-16-0986-2 ISBN 978-981-16-0987-9 (eBook) , ttps://doi.org/10.1007/978-981-16-0987-9 | | | | | | | | | |
| **Related Online Contents [MOOC, SWAYAM, NPTEL, Websites etc.]** | | | | | | | | | | |
| 1 | <https://nptel.ac.in/courses/102104042> | | | | | | | | | |
| 2 | <https://nptel.ac.in/courses/102103044> | | | | | | | | | |
| 3 | <https://nptel.ac.in/courses/102106065> | | | | | | | | | |
| 4 | <https://www.coursera.org/learn/drug-discovery-development> | | | | | | | | | |
| Course Designed By: **Dr. J. ANGAYARKANNI** | | | | | | | | | | |
| **Mapping with Programme Outcomes** | | | | | | | | | | |
| **COs** | | **PO1** | | **PO2** | **PO3** | **PO4** | | **PO5** | | **PO6** | |
| **CO1** | | L | | L | S | L | | L | | M | |
| **CO2** | | L | | L | S | L | | L | | L | |
| **CO3** | | L | | L | S | L | | L | | L | |
| **CO4** | | L | | L | S | L | | L | | L | |
| **CO5** | | L | | L | S | L | | L | | L | |

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| **Course code** | | | | **23MBTAC05** | | | | | **CELL CULTURE TECHNIQUES** | | | | | | | **L** | | | | **T** | **P** | **C** |
| **Core Paper** | | | | | | | | | **3** | | | | **1** | **1** | **5** |
| **Pre-requisite** | | | | | | | | | Basic knowledge on plants and animal cells | | | | | | | **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 micro propagation 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 | |
| 5 | | Acquire knowledge on stem cell biology | | | | | | | | | | | | | | | | | | | K3 | |
| **K1**-Remember;**K2**-Understand;**K3**-Apply;**K4**-Analyze;**K5**-Evaluate;**K6**–Create | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
| **Unit:1** | | | | | | | **INTRODUCTION** | | | | | | | | | | **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.  **Practical:**   * Preparation of MS medium. * Callus induction * Suspension cell culture | | | | | | | | | | | | | | | | | | | | | | |
| **Unit:2** | | | | | | | **MICROPROPAGATION** | | | | | | | | | | **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.  **Practical:**   * Synthetic seed preparation * Protoplast isolation and fusion. | | | | | | | | | | | | | | | | | | | | | | |
| **Unit:3** | | | | | | | **APPLICATIONS OF PLANT TISSUE CULTURE** | | | | | | | | **10hours** | | | | | | | |
| Somaclonal variation – Causes and significance, plant tissue culture in forestry,, clonal propagation, production of useful biochemicals – Gene conservation bank – plant tissue culture in biotechnology-commercial aspects of plant tissue culture.  **Practical:**   * Micro propagation | | | | | | | | | | | | | | | | | | | | | | |
| **Unit:4** | | | | | | | **ANIMAL TISSUE CULTURE** | | | | | | | | **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** | | | | | | **APPLICATIONS OF ANIMAL TISSUE CULTURE** | | | | | | | | | | | | **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:asteptowardlabanimalreduction https://[www.biocompare.com/Editorial-Articles/351896-Realizing-New-Possibilities-for-Cell-Line-](http://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/S2452310018300027](http://www.sciencedirect.com/science/article/pii/S2452310018300027)https://jandeboerlab.com/research/computational-sciences/machine-learninghttps://[www.nature.com/articles/s41598-019-50208-x](http://www.nature.com/articles/s41598-019-50208-x) | | | | | | | | | | | | | | | | | | | | | | |
| **E-learning 2hours** | | | | | | | | | | | | | | | | | | | | | | |
| https://[www.nature.com/articles/s41598-020-60278-x](http://www.nature.com/articles/s41598-020-60278-x)https://[www.frontiersin.org/articles/10.3389/fpls.2016.00274/full](http://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-](http://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. | | | | | | | | | | | | | | | | | | | | | |
| **Reference Books** | | | | | | | | | | | | | | | | | | | | | | |
| 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. MartinusNijhoff 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, Websites etc.]** | | | | | | | | | | | | | | | | | | | | | | | |
| 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** | | | | | | **PO7** | | | | |
| **CO1** | | | | | L | | | L | | L | S | L | L | | | | | | L | | | | |
| **CO2** | | | | | L | | | L | | L | S | L | L | | | | | | L | | | | |
| **CO3** | | | | | L | | | L | | L | S | L | L | | | | | | M | | | | |
| **CO4** | | | | | L | | | L | | L | S | L | L | | | | | | M | | | | |
| **CO5** | | | | | L | | | L | | L | S | L | L | | | | | | L | | | | |

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| **Course code** | | **23MBTAC06** | | | | | | **FUNDAMENTALS OF FERMENTATION TECHNOLOGY** | | | | | | **L** | | | | | **T** | **P** | **C** |
| **Core Paper** | | | | | | | | **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 fermented designing and kinetics involved in the fermentation processes. 2. Aims to empower the students with various designs of fermented. | | | | | | | | | | | | | | | | | | | | | |
| **Expected Course Outcomes:** | | | | | | | | | | | | | | | | | | | | | |
| On the successful completion of the course, student will be able to: | | | | | | | | | | | | | | | | | | | | | |
| 1 | Gain wide information about types of ferment | | | | | | | | | | | | | | | | | | | K2 | |
| 2 | Design a production protocol for a microbial product | | | | | | | | | | | | | | | | | | | K6 | |
| 3 | Formulate fermentation condition required for the product of interest. | | | | | | | | | | | | | | | | | | | K6 | |
| 4 | Design purification method of any fermentation product | | | | | | | | | | | | | | | | | | | K6 | |
| 5 | Formulate any product for commercialization | | | | | | | | | | | | | | | | | | | K6 | |
| **K1**-Remember;**K2**-Understand;**K3**-Apply;**K4**-Analyze;**K5**-Evaluate;**K6**–Create | | | | | | | | | | | | | | | | | | | | | |
| **Unit:1** | | | | | | **TYPES AND DESIGN OF BIOREACTOR** | | | | | | | | | **10hours** | | | | | | |
| **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** | | | | | | **PROCESS KINETICS** | | | | | | | | | **15hours** | | | | | | |
| **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 coimmobilization; **Chemical kinetics** and classification of chemical reactors. **Transport phenomena**- Mass transfer, heat transfer, oxygen transfer; transfers in immobilized cells. | | | | | | | | | | | | | | | | | | | | | |
| **Unit:3** | | | | | | **PRODUCTION KINETICS** | | | | | | | **10hours** | | | | | | | | |
| 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** | | | | | | **DOWNSTREAM PROCESSING** | | | | | | | **10hours** | | | | | | | | |
| 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** | | | | **QUALITY ANALYSIS** | | | | | | | | | | | | **13hours** | | | | | |
| 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** | | | | | | | | | | | | | **3 hours** | | | |
| [**https://doi.org/10.1016/j.biortech.2022.128451**](https://doi.org/10.1016/j.biortech.2022.128451) | | | | | | | | | | | | | | | | | | | | | |
| [**https://doi.org/10.1093/bbb/zbab188**](https://doi.org/10.1093/bbb/zbab188) | | | | | | | | | | | | | | | | | | | | | |
| [**https://doi.org/10.3390/fermentation8040137**](https://doi.org/10.3390/fermentation8040137) | | | | | | | | | | | | | | | | | | | | | |
| **E-learning 2hours** | | | | | | | | | | | | | | | | | | | | | |
| SWAYAM-https://[www.classcentral.com/course/swayam-principles-of-downstream-](http://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](https://nptel.ac.in/courses/102/106/102106083/TransportPhenomena%20in%20Biological%20Systems-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 | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | |
| **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-](http://www.classcentral.com/course/swayam-principles-of-downstream-)  techniques-in-bioprocess-3967 | | | | | | | | | | | | | | | | | | | | |
| 2 | NPTELhttps://nptel.ac.in/courses/102/105/102105064/#AspectsofBiochemicalEngineering, Prof.DebabrataDas,IITKharagpur | | | | | | | | | | | | | | | | | | | | |
| 3 | NPTEL - [https://nptel.ac.in/courses/102/106/102106083/TransportPhenomena in Biological Systems-Prof.Suraish](https://nptel.ac.in/courses/102/106/102106083/TransportPhenomena%20in%20Biological%20Systems-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** | | | M | | | | L | | L | L | S | | | | | | S | | | | |
| **CO2** | | | M | | | | L | | L | M | S | | | | | | S | | | | |
| **CO3** | | | M | | | | L | | L | M | S | | | | | | S | | | | |
| **CO4** | | | M | | | | L | | L | L | S | | | | | | S | | | | |
| **CO5** | | | M | | | | L | | L | L | S | | | | | | S | | | | |

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| **Course code** | | | | | **24MBTAGE01** | | **GOOD MANUFACTURING PRACTICES AND QUALITY ASSURANCE** | | | | | | | **L** | | | **T** | | **P** | **C** |
| **Elective Paper** | | | | | | | **4** | | | **-** | | **-** | **4** |
| **Pre-requisite** | | | | | | | **Basic knowledge on practices in bio process industry** | | | | | | | **Syllabus Version** | | | | **2024-25** | | |
| **Course Objectives:** | | | | | | | | | | | | | | | | | | | | |
| The main objectives of this course are to:   1. Provide the student with an understanding of the principles and practice of GMP 2. Enable them to realize the importance and compliance of GMP. 3. Impart Expertise on the Administrative structure in the Industries 4. Will be taught about the designing an Industry and construction of SOPs 5. Learning on Artificial Intelligence role in Industry 4.0 | | | | | | | | | | | | | | | | | | | | |
| **Expected Course Outcomes:** | | | | | | | | | | | | | | | | | | | | |
| On the successful completion of the course, student will be able to: | | | | | | | | | | | | | | | | | | | | |
| 1 | | Select and design the facilities in the Industry | | | | | | | | | | | | | | | | | K3 | |
| 2 | | systematize the arrangement of equipment and recruitment of personnel in the Industry | | | | | | | | | | | | | | | | | K5 | |
| 3 | | Perform quality check for the raw materials and products | | | | | | | | | | | | | | | | | K3 | |
| 4 | | Acquire knowledge on the administrative processes in the Industry and regulations of different regulatory bodies | | | | | | | | | | | | | | | | | K4 | |
| 5 | | Understand the process of quality assuranse | | | | | | | | | | | | | | | | | K2 | |
| **K1** - Remember; **K2** - Understand; **K3** - Apply; **K4** - Analyze; **K5** - Evaluate; **K6** – Create | | | | | | | | | | | | | | | | | | | | |
| **Unit:1** | | | | | **BASIC PRINCIPLES** | | | | | | | | | | | **-- hours** | | | | |
| **Principles, activities and Importance of GMP** – Definition of GMP, activities, Quality management, Personnel and training, personal hygiene and sanitation, premises and equipment, production, Quality control (including GLP, retained samples, stability study), Documentation, Inspections (self - inspection and quality audits), product complaints, product recall and returned products, validation | | | | | | | | | | | | | | | | | | | | |
| **Unit:2** | | | | | **MANAGEMENT** | | | | | | | | | | **-- hours** | | | | | |
| **Premises** - Design, construction, and maintenance of the production and staff areas in the facility, Layout (design) of the facility - separation from farm/animals/pets (small scale) - perimeter, entrances, drainage - construction, heating/ventilation, humidity control, product flow - equipment / pipe layout / drainage - water source (treatment, hardness) monitoring  **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** | | | | | **PROCESS CONTROL** | | | | | | | | **-- hours** | | | | | | | |
| **Raw Material Testing** - Analysis of raw materials, developing specification, purchase specifications and maintenance of stores for raw materials. Accepting raw materials from a vendor without additional regular testing - Supplier certification. Self-inspection programs for fabricators, packagers/labelers - Testing requirements for packaging materials including supplier certification. **Good practices in production and process control** - Controlling the manufacturing process - Stages in the production cycle – contracting quality tools – R & D –  **Process Control** - refrigeration, pasteurization - culture, pH, incubation temperature. **Finished Product Testing** - Finished product testing - Writing product specifications - Conditions and options for finished product testing, - product storage - packaging, distribution. | | | | | | | | | | | | | | | | | | | | |
| **Unit:4** | | | | | **QUALITY CONTROL** | | | | | | | | **-- hours** | | | | | | | |
| **Quality Control Department and Audits** – Establishment of a QC department – Responsibilities of QC and Investigation of product quality. Audits - Records – Maintenance of accurate, clear, and precise documents - Identifying individuals responsible for maintaining documents. Validation - Definition – PQ, DQ, OQ, IQ Qualification, Process validation and Computer validation. Calibration and validation of various instruments used for drug analysis - UV Visible Spectrophotometer, IR spectrophotometer, spectrofluorometer, HPLC, HPTLC and GC. GMP regulations - US-FDA, Europe, Japan, ICH, PICS/S, WHO. | | | | | | | | | | | | | | | | | | | | |
| **Unit:5** | | | | | **QUALITY ASSURANCE** | | | | | | | **-- hours** | | | | | | | | |
| **QA** - Definition of QA, activities and functions. Quality: Concept of quality, nature of product quality, details of international standards (ISO, GMP, GLP and ISI). Role of quality audit in quality assurance. Process management, project management, strategic development and product development. Measurement of quality, information and decision making or utilization of data. Quality operations, its inspection and test used for it. Human resource and training for quality. Computerized system - software development, computer applications and quality system. Requirements of product registration, in India and other countries. | | | | | | | | | | | | | | | | | | | | |
| **Unit:6** | | | | | **Contemporary Issues** | | | | | | | **2 hours** | | | | | | | | |
| 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** | | | | | | | **62-- hours** | | | | | | | | |
| **Text Book(s)** | | | | | | | | | | | | | | | | | | | | |
| 1 | | | Compendium of Good Practices in Biotechnology, BIOTOL series | | | | | | | | | | | | | | | | | |
| **Reference Books** | | | | | | | | | | | | | | | | | | | | |
| 1 | .**A WHO guide to good manufacturing practice (GMP) requirements: Volume 1,2,3,4,5. Part 2-Validation, by** Gillian Chaloner-Larsson, Ph.D. GCL Bio consult, Ottawa | | | | | | | | | | | | | | | | | | | |
| 2 | **Good Manufacturing Practices for Pharmaceuticals, Sixth Edition by: Graham Bunn** Publisher: Informa Healthcare; 6 edition | 424 pages (2007) <http://ebookee.org/Good-Manufacturing-Practices-for-Pharmaceuticals-Sixth-Edition_859976>. html#uPYoXd8huFeqqXB9.99 | | | | | | | | | | | | | | | | | | | |
| 3. | A Primer – Good Laboratory Practices and current manufacturing practice, by Ludwig Huber, 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, Websites etc.]** | | | | | | | | | | | | | | | | | | | | |
| 1 | Inspection and Quality Control in Manufacturing-<https://swayam.gov.in/nd1_noc20_me27/preview> | | | | | | | | | | | | | | | | | | | |
| 2 | Product design and Manufacturing-<https://swayam.gov.in/nd1_noc20_me12/preview> | | | | | | | | | | | | | | | | | | | |
| 3 | Design for quality manufacturing and assembly-<https://swayam.gov.in/nd1_noc19_me48/preview> | | | | | | | | | | | | | | | | | | | |
| 4. | Quality Design and Control-<https://swayam.gov.in/nd1_noc20_mg18/preview> | | | | | | | | | | | | | | | | | | | |
| **Course Designed By: Dr. A. PREMKUMAR and Dr. V. BRINDHA PRIYADARISINI** | | | | | | | | | | | | | | | | | | | | |
| **Mapping with Programme Outcomes** | | | | | | | | | | | | | | | | | | | | |
| **COs** | | | | **PO1** | | **PO2** | | **PO3** | **PO4** | **PO5** | **PO6** | | | | | | | | **PO7** | |
| **CO1** | | | | L | | L | | L | L | L | L | | | | | | | | S | |
| **CO2** | | | | L | | L | | L | L | L | L | | | | | | | | S | |
| **CO3** | | | | L | | L | | L | L | L | L | | | | | | | | S | |
| **CO4** | | | | L | | L | | L | L | L | L | | | | | | | | S | |
| **CO5** | | | | L | | L | | L | L | L | L | | | | | | | | S | |