



**Deccan Education Society's
Fergusson College
(Autonomous)
Pune**

**Learning Outcomes-Based Curriculum
for 4 years B.Sc. Programme (Honors)**

as per guidelines of

NEP-1.0

for

Fourth Year B. Sc. (Honours) - Biotechnology

With effect from Academic Year

2026-2027



Deccan Education Society's

Fergusson College (Autonomous), Pune-4

Department of Biotechnology

Syllabi NEP 1.0 Implemented from Academic Year 2026-27

Fourth Year BSc. Biotechnology**Semester: VII /VIII****Program Specific Outcomes (PSOs)**

PSO	Outcomes
PSO1	Academic competence: - Gain strong foundation and knowledge in scientific fundamentals and acquire comprehensive understanding of the principles and practices of biotechnology including skill-based concepts, in an interdisciplinary course structure, provided by highly qualified and competent faculty. - Acquire training in techniques/skills utilised in biotechnology and understand the scope and applications of biotechnology in well-equipped and state of the art laboratories. - Achieve competence for higher studies, research and be employment ready in the domain of Biotechnology and allied field. - Demonstrate qualities of a responsible biotechnologists that can work within the interdisciplinary framework of biotechnology and related fields.
PSO2	Personal and Professional Competence: - Analyze and interpret data and provide solutions to basic problems relevant to biotechnology and related fields. - Apply appropriate tools and techniques in biotechnology, combine experimental and computational approaches to design and perform experiments proficiently. - Demonstrate and apply knowledge and skill in the design and development of solutions for relevant problems to cater to the requirements of biotechnology industries - Acquire good oral and written communication skills Experience the opportunity to curate/ manage or participate in a variety of co and extracurricular activities like internships, research projects, field projects, that will cater to professional demands by the Industry, Research institutes and overall personality development
PSO3	Research Competence: - Develop an interdisciplinary approach to conduct original research in various field of Biotechnology and allied fields - Demonstrate appropriate skills in design of experiments with appropriate controls, critical thinking and result analysis - Apply statistical skills and computational tools to explore, analyse and authenticate biological data in experiments and research
PSO4	Entrepreneurial and Social competence: - Implement skills and knowledge acquired in skill imparting and entrepreneurial courses in upcoming fields of Biotechnology - Develop a sense of social, ethical, environmental and professional responsibility - Practise professional ethics in the conduct of Science - Recognize the importance of Bioethics, IPR, entrepreneurship, Communication, management skills and community engagement programmes to be ready to pursue a future course of career.

Fergusson College (Autonomous), Pune Department of Biotechnology Programme: B.Sc. Biotechnology Course Structure NEP UG4 BSc (NEP 1.0) UG4 BSc NEP 1.0				
Semester	Paper Code	Paper Title	Theory/Practical	Credits
VII	BTH-401	Omics and their applications in Biotechnology	Theory	4
	BTH-402	Animal and Plant Biotechnology	Theory	4
	BTH-403	Clinical Biotechnology	Theory	4
	OR			
	BTH-404	Bioentrepreneurship and IPR	Theory	4
	BTH-445	Research Methodology	Theory	4
	BTH-411	Biotechnology Practicals-11	Practical	2
	BTH-412	Biotechnology Practicals-12	Practical	2
	Total semester credits			20
VIII	BTH-451	Stem cell, regenerative medicine and cancer biology	Theory	4
	BTH-452	Industrial Biotechnology	Theory	4
	BTH-453	Clinical Research and Data Management	Theory	4
	OR			
	BTH-454	Food Biotechnology	Theory	4
	BTH-495	On Job Training/Field Project	Theory/Practical	4
	BTH-461	Biotechnology Practicals-13	Practical	2
	BTH-462	Biotechnology Practicals-14	Practical	2
	Total semester credits			20
Total UG-4 Credits				40

BTH- 401	Omics studies and their applications in Biotechnology Major-Theory	
	No. of Credits: 4 No. of Hours: 60	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's Cognitive Level
CO1	State concepts related to genome, transcriptome, proteome and metabolome.	1
CO2	Explain advantages and limitations of structural and functional genomics, proteomics and transcriptomics.	2
CO3	Illustrate concepts related to genome organization, mapping, transcriptome and proteome annotation and sequencing using databases and bioinformatics tools.	3
CO4	Explain applications of genomics, transcriptomics, proteomics and metabolomics in various fields	4
CO5	Discuss the advantages and limitations of various metabolomics techniques.	5
CO6	Integrate proteomics and metabolomics strategies in a variety of applications.	6

**BTH- 401: Omics studies and their applications in Biotechnology
Major-Theory**

Sr. No	Topic	Total No. of hours (60)
	Genomics	25
I	Structural and functional Genomics, Mapping of genomes, Next generation sequencing methods, Genome sequence assembly, Genome Annotation, Genome evolution and Comparative Genomics. Databases and tools for DNA sequencing, assembly and analysis.	15
II	• Applications: Epigenomics, Pharmacogenomics. • Microbiome: Concept, Microbiome and Human health (examples) • Pangenomes and cyberbiosecurity: Concept and applications.	10
	Transcriptomics	10
I	• RNA-Seq Data- Acquisition, Read mapping, Gene quantification, Differential expression analysis, Volcano plots and heat maps and Expression quantification methods. Analysis using Microarray databases and softwares. • Applications.	10
	Proteomics	20
I	• Types of Proteomics • Different workflows and methodologies • Strategies in protein identification and quantification. • Expression, Structural and Functional proteomics.	10

	Advantages and limitations of Structural and Functional Proteomics.	
II	Proteomics databases and allied bioinformatics tools and data analysis.	10
	Metabolomics	5
I	Introduction, Concept, Advantages and limitations of Targeted and Non targeted metabolomics.	2
II	Techniques in Metabolomics - Sample Preparation techniques - Strategies in Metabolite identification - Databases and data analysis - Applications.	3
	Reading of current research publications in all modules.	

Learning Resources

Sr. No	References
1	Molecular cloning – a laboratory manual – (Vol. 1-3), 4rd edition, (2012), Green and Sambrook, Cold Spring Harbor Laboratory Press, USA
2	Principles of Gene Manipulation & Genomics, 7th Edition (2006), Primrose and Twyman, Blackwell Publishing, USA.
3	Alonso A, Marsal S and Julià A (2015) Analytical methods in untargeted metabolomics: state of the art in 2015. Front. Bioeng. Biotechnol. 3:23. doi: 10.3389/fbioe.2015.00023.
4	Zhan, X. (Ed.). (2021). Metabolomics - Methodology and Applications in Medical Sciences and Life Sciences. IntechOpen. doi: 10.5772/intechopen.90987
5	Wang, Y., Li, S., Nong, B., Zhou, W., Xu, S., Songyang, Z. and Xiong, Y., 2023. Comprehensive RNA-Seq analysis pipeline for Non-Model organisms and its application in Schmidtea mediterranea. Genes, 14(5), p.989.
6	Cornwell, M., Vangala, M., Taing, L., Herbert, Z., Köster, J., Li, B., Sun, H., Li, T., Zhang, J., Qiu, X. and Pun, M., 2018. VIPER: Visualization Pipeline for RNA-seq, a Snakemake workflow for efficient and complete RNA-seq analysis. BMC bioinformatics, 19(1), p.135.
7	Richard Twyman. Principles of Proteomics. 1st ed. London: Taylor & Francis, 2004
8	Malcolm Campbell, and Laurie J. Heyer, Discovering genomics, Proteomics and Bioinformatics. 2nd ed. USA: Benjamin Cummings, 2006.
9	https://www.uniprot.org/ https://www.expasy.org/
10	https://www.matrixscience.com/
11	https://www.metabolomicsworkbench.org/data/index.php
12	http://www.metabolomexchange.org/site/ https://www.ebi.ac.uk/metabolights/

BTH-402	Animal and Plant Biotechnology Major-Theory	
	No. of. Credits: 4 No. of. Hours: 60	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's Cognitive Level
CO1	Explain the fundamental concepts of animal cell culture systems including monolayer and organotypic/histotypic cultures.	1
CO2	Describe animal breeding and reproductive biotechnologies	2
CO3	Demonstrate understanding of advanced plant tissue culture techniques.	3
CO4	Explain the biosynthesis and applications of plant secondary metabolites and analyze plant responses to abiotic stresses	4
CO5	Compare and evaluate traditional and modern plant breeding techniques for crop improvement.	5
CO6	Illustrate the principles and techniques of genetic engineering in plants	6

**BTH-402: Animal and Plant Biotechnology
Major-Theory**

Sr. No	Topic	Total No. of hours (60)
	Animal Biotechnology	20
I	Concept of monolayer vs organotypic/Histotypic and their applications in animal biotechnology	4
II	Animal breeding and reproductive biotechnology • Livestock breed and their productivity, artificial breeding methods and hazards, marker assisted breeding of livestock. • Somatic cell-nuclear transplant • Assisted Reproductive Technologies: Hormonal Manipulations, <i>in vitro</i> fertilization, embryo transfer technology, artificial insemination, gamete preservation, sex determination and sexing of embryos, germ cell storage.	6
III	Molecular markers in animal genomics • Introduction to animal genomics, different methods for characterization of animal genomes, SNP, STR, QTL, RFLP, RAPD, genetic basis for disease resistance, Nutritional and metabolic trait enhancement • Genome-wide association studies (GWAS)	4
IV	Other Applications • Application of animal cell culture for <i>in vitro</i> testing of drugs. • Bioassays using animals and cell lines: examples of <i>in-vitro</i> and <i>in-vivo</i> studies • Hybridoma Technology • Virus propagation	6

	Plant Biotechnology	40
I	Advanced Plant Tissue Culture Techniques • Meristem Tip Culture • Protoplast Culture and Somatic Hybridization • Haploid Production • Embryo and Endosperm Culture	4
II	Secondary metabolites • Types of Secondary Metabolites and Biochemical Pathways. • Induction of Plant Secondary Metabolism and Production by Inducer and Precursor • Methods for the Isolation and Structure Elucidation of Metabolites • The Role of Plant-Derived Natural Products in Drug Innovation.	6
III	Responses of plants to drought, salinity and temperature stress • Drought stress – effects on growth and metabolism in plants Adaptive responses to drought stress, drought escape, tolerance • Salinity stress – Osmotic and ionic effects on growth and metabolism Mechanisms for removal of sodium from cells - SOS pathway. • Temperature Stress – Effects on growth and metabolism.	8
IV	Traditional and Newer Techniques in Plant Breeding • Breeding methods in self, cross pollinated and clonally propagated crops: Pureline selection, Pedigree selection, Bulk method, Backcross method. • Mutation breeding: Types, Mutagens: Physical and chemical mutagens, Mutant types, Role of mutation in breeding. Role of polyploidy in plant breeding • Molecular Markers and Marker Assisted Selection (MAS) Morphological Markers Biochemical Markers. • Non-PCR based and PCR based approaches (RAPD, AFLP, SSR, SNP, STR). • QTL Mapping and Marker Assisted Selection (MAS), • Marker Assisted Gene Pyramiding	10
V	Production of Transgenic plants • Gene Transfer Techniques: Agrobacterium mediated Transformation, Virus mediated Gene transfer, Direct DNA transfer to plants – Electroporation, biolistic transfer • Genome Editing and Alteration of Gene Expression: Site-directed mutagenesis, Insertional mutagenesis, knock out mutants, targeting induced local lesions in genomes (TILLING), CRISPR-Cas genome editing technology. • Gene silencing - Gene inhibition at RNA level - antisense, co-suppression, miRNAs and siRNAs. Silencing mechanisms • Factors affecting transformation, Screening and analysis of transformants. Applications of Transgenic Technology in Plants • Resistance against pathogens and pests – Case studies • Abiotic stress tolerance – Case studies.	10

	Improvement of crop quality-Case Studies	
VI	Regulations regarding GMOs– Potential problems with GMOs, efforts to prevent these problems. Arguments in the GMO Controversy	2
	Reading of current research publications in all modules.	

Learning Resources

Sr. No	References
1	R. Ian Freshney. Culture of Animal cells, 5th Edition, 2010. A John Wiley & Sons, Inc., Publications, USA
2	R.W.Masters. Animal Cell Culture- Practical Approach, 3rd Edition ,2000, Oxford University Press. USA
3	Robert Lanza et al. Essentials of Stem Cell Biology”, Academic Press, 2nd edition, 2006.USA
4	Text book of Animal Husbandry, 8th edition, (1998) G.C. Banerjee,Oxford and IBH Publishing co. Pvt. Ltd. India
5	Molecular Biotechnology: 4th edition. (2010), Glick B.R., Pasternak J.J., Patten C. L., ASM press, USA
6	Gene Transfer to Animal Cells, 1st edition (2005), R. M. Twyman, Taylor & Francis USA.
7	Chawla, H. C. (2004) Introduction to Plant Biotechnology
8	Davies k (2004) –Plant Pigments and their Manipulation-Annual Plat Reviews-Vol 14
9	Altman,A and Hasegawa P M (2012) – Plant Biotechnology and Agriculture Prospects for the 21st century
10	Bhojwani,S S and Razdan M.K.(1996) plant Tissue Culture: Theory and Practices
11	Slater A, Scott,N W, Fowler, M R (2008) –Plant Biotechnology: Genetic manipulation of plants
12	Lincoln Taiz and Eduardo Zeiger (2010) Plant Physiology, Fifth edition. Sinauer Associates, Inc. Publishers. Sunder land,

BTH-403	Clinical Biotechnology (Elective Theory)	
	No. of Credits: 04 No. of Hours:60	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's cognitive level
CO1	Understand the stages of the diagnostic cycle (pre-analytical, analytical, and post-analytical) and the physiological basis of common laboratory tests.	1
CO2	Select & interpret various metabolic panels (BMP, CMP, LFT) and lipid profiles to suggest appropriate investigations for chronic or infectious diseases.	2
CO3	Outline the technical protocols for handling clinical specimens and performing classical diagnostic techniques like serology, biopsy, and immunohistochemistry.	3
CO4	Analyze pathology reports (CBC, hormone testing, and imaging) to identify diagnostic errors and correlate findings with specific systemic disorders.	4
CO5	Evaluate molecular diagnostic tools and genetic testing methods based on their accuracy, clinical utility, and adherence to safety and regulatory standards.	5
CO6	Integrate and formulate diagnostic strategies that incorporate emerging technologies like AI and Point-of-Care testing while upholding ethical standards and patient confidentiality.	6

**BTH-403: Clinical Biotechnology
(Elective Theory)**

Sr. No	Topic	Total No. of hours (60)
I	Introduction to Diagnostic cycle: Pre-analytical, Analytical and Post-analytical.	1
II	Laboratory tests for infectious agents Guidelines for the collection, Transport, Processing, Analysis and Reporting of Cultures from specific specimen sources like respiratory tract, gastrointestinal tract, urinary tract, genital tract, CNS.	4
III	Understanding Pathology Lab reports and their implications in various diseases/disorders - Complete Blood Count (CBC)- red and white blood cells, platelets, haemoglobin and haematocrit levels. - Basic Metabolic Panel (BMP): kidney function, blood sugar, and electrolyte balance. - Comprehensive Metabolic Panel (CMP) and Liver function tests (LFT): chronic diseases, liver function, liver damage,	15

	hepatitis, and monitors liver-related conditions and mineral imbalances. ● Lipid Panel: Cholesterol, triglyceride, HDLs, LDLs, VLDLs, cardiovascular risk and cholesterol levels in obesity. ● Pulmonary Function and bone density tests ● Hormone and Vitamins Testing: Thyroid function, Vitamin D and B12 tests.	
	Diagnostics	40
I	Classical ● Serological tests for Viral/Bacterial Infections, Autoimmune disorders, Immune status ● Biopsy ● Endoscopy ● Histopathology: Introduction to collection, preparation and processing of the samples, interpretation of the slides in various diseases like myocardial infarctions and infectious diseases ● Immunohistochemistry, immunofluorescence and multiplex approaches. ● Automated commercial systems	20
II	Molecular Diagnosis: Current trends and case studies ● Detection and identification of diseases: Bacterial, viral diseases and parasitic infections. Molecular Diagnostics in Genetic and inherited disorder detection: ● Genetic Counselling, Ethical concerns, regulations and approved testing ● Types of genetic testing (diagnostic, predictive, carrier and prenatal etc.). ● Detection of inherited disorders (chromosomal and single-gene) including prenatal testing and pre-implantation diagnosis.	15
III	● Future Trends concepts and applications: Point-of-Care Testing, Artificial Intelligence (AI), Integration with Electronic Health Records (EHRs)	5
	Reading of current research publications in all modules.	

Learning Resources

Sr. No	References
1	Robbins, S.L.; Pathological basis of Disease; 9th Edition; (2015); W B Saunders Publishing.
2	Macleod, J.; Davidson's Principles & Practice of Medicine; A textbook for students and doctors' 14th Edition. Churchill Livingstone.
3	Guyton, A.C. and Hall, J.E.; Textbook of Medical Physiology 11th Edition; (2006). W B Saunders Publishing.
4	Hage, D. S. and Carr, J. D.; Analytical Chemistry & Quantitative Analysis; (2010); Prentice Hall. 5. Berg, J.M., Tymoczko, J. L. and Stryer L.; Biochemistry, 5th Edition.
5	Koneman's Color Atlas and Textbook of Diagnostic Microbiology, 7th Edition. Wolters Kluwer, Lippincott Williams & Wilkins.
6	Coleman, W. B., & Tsongalis, G. J. (2010). Molecular Diagnostics: for the Clinical Laboratorian. Totowa, NJ: Humana Press
7	Elles Rob and Mountford, R(2004), Molecular Diagnosis of Genetic Diseases (Second Edition), Springer
8	https://www.pdfdrive.com/konemans-color-atlas-and-textbook-of-diagnostic-microbiology-e184259636.html
9	https://www.google.co.in/books/edition/Introduction_to_Diagnostic_Microbiology/zl0PEAAAQBAJ?hl=en&gbpv=1&dq=diagnostic+microbiology&printsec=frontcover
10	Diagnostic Techniques: Serological and Molecular Approaches - PMC

BTH- 404	Bioentrepreneurship and IPR (Elective Theory)	
	No. of Credits: 4 No. of Hours: 60	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's Cognitive Level
CO1	Outline and discuss various types of entrepreneurships, various motivational theories of entrepreneurship and policies of government.	1
CO2	Define various steps for project proposal identification and selection of projects; project report: contents and formulation.	2
CO3	Discuss the role of government agencies in entrepreneurship and various funding opportunities available through government and private investors.	3
CO4	Explain the importance of IPR in Biotechnology	4
CO5	Analyze the environmental risk and understand the importance of development plan	5
CO6	Review case studies related to the bioethics, biosafety and regulation concepts so as to gain a critical understanding of their contents.	6

**BTH- 404: Bioentrepreneurship and IPR
(Elective Theory)**

Sr. No	Topic	Total No. of hours (60)
	Bioentrepreneurship	30
I	Basics of Bioentrepreneurship: ● Importance of entrepreneurship; advantages of being entrepreneur - freedom to operate; introduction to bioentrepreneurship – biotechnology in a global scale; ● Scope in Bioentrepreneurship; types of bio-industries – biopharma, bioagri, bioservices and bioindustrial; innovation – types, out of box thinking; skills for successful entrepreneur – creativity, leadership, managerial, team building, decision making; ● Opportunities for Bioentrepreneurship: Entrepreneurship development programs of public and private agencies (MSME, DBT, BIRAC, Startup & Make in India); patent landscape, IP protection & commercialization strategies. ● Women led Entrepreneurship	6
II	Accounting and Finance: ● Business plan preparation; business feasibility analysis by SWOT, socio-economic costs benefit analysis; funds/support from Government agencies like MSME/banks and private agencies like venture capitalists:/angel investors for bioentrepreneurship.	6

	● Business plan proposal for „virtual startup company“; statutory and legal requirements for starting a company/venture; basics in accounting practices: concepts of balance sheet, profit and loss statement, double entry bookkeeping.	
III	BioEconomy Collaborations and Partnerships: ● Bio-economics- Concept, Development of Economics and Bioscience (Concept of resource economics for scarcity of biological resources), Bioresource elasticity, Evolution and Development of Economics and Biology (Charles Darwin and the evolutionary paradigm). Introduction to bio-business, from the Indian context, SWOT analysis of bio- business. Ownership, Development of Entrepreneurship; Stages in entrepreneurial process ● Role of entrepreneurs in Economic Development; Entrepreneurship in India; Entrepreneurship, its ● barriers. Small scale industries: Definition; Characteristics; Need and rationale; Objectives; Scope; Market ● Feasibility Study; Technical Feasibility Study; Financial Feasibility Study & Social Feasibility Study. Global bio business and industry future trends. ● Collaborations & partnerships; information technology for business administration and expansion.	6
IV	Business Strategy and Marketing: ● Entry and exit strategy; pricing strategy; negotiations with financiers, bankers, government and law enforcement authorities; dispute resolution skills ● External environment/ changes; avoiding/managing crisis; broader vision–global thinking; mergers & acquisitions. ● Market conditions, segments, prediction of market changes, Identifying needs of customers, Market linkages, branding issues, Developing distribution channels - franchising; policies, promotion, advertising, Branding and market linkages for virtual startup company.	6
V	Knowledge Centre and R&D ● Knowledge centres e.g., in universities, innovation centres, research institutions (public & private) and business incubators, R&D for technology development and upgradation; assessment of technology development, managing technology transfer, industry visits to successful bio-enterprises, regulations for transfer of foreign technologies, Quality control, technology transfer agencies, Understanding of regulatory compliances and procedures (CDSCO, NBA, GLP, GCP, GMP) ● Business opportunity, Essential requirement, marketing strategies, schemes, challenges and scope-with case study- Pollution monitoring and Bioremediation for Industrial pollutants, Pesticides, Herbicides etc. ● Business opportunity, Essential requirement, marketing, strategies, schemes, challenges and scope-with case study on Plant cell and tissue culture technique, poly house culture. ● Herbal bulk drug production, Nutraceuticals, value added herbal products.	6

	• Bio ethanol production using Agri waste, Algal source. Integration of system biology for agricultural applications. Biosensor development in Agri management • Integrated compost production- microbe enriched compost. Bio pesticide/insecticide production • Fermented products-probiotic and prebiotics. Stem cell production, stem cell bank, contract research. Production of monoclonal/polyclonal antibodies, Single cell protein and secondary metabolite production. Contract research in microbial genomics.	
	Intellectual Property Rights (IPR)	30
I	Introduction to IPR • Definition, Concept and Nature of Intellectual Property, Origin and Development of Intellectual Property • Distinction between Intellectual Property and other tangible and intangible properties, Kinds of Intellectual Property, Need for Protecting Intellectual Property- National Intellectual Rights Policy. Importance of Intellectual Property in the present era, Monopoly v. Public Interest	5
II	Various form of IPR • Introduction to patents: Basics of Patents, Conditions of Patentability, Patentable Subject Matter, Industrial Applicability (Utility), Novelty, Inventive Step (Non-Obviousness) • Introduction to Industrial Designs: Introduction to Industrial Designs, Legal Protection of Industrial Designs, Subject matter of Protection, Exclusion of Designs, Novelty or Originality, Rights in Industrial Design, Entitlement of Rights, Acquisition of Rights, Duration of Rights. • Introduction of trademark: Introduction to Trademarks, Definition of Signs Which May Serve as Trademarks, Criteria of Protectability and Requirement of Distinctiveness deceptiveness Trademark Assignment and Licensing.	5
III	Other legal forms of IP • Introduction to Geographical Indications of Goods: Historical background of law of Geographical Indications in India Meaning and Definition, Functions and Characteristics of Geographical Indication Distinction between Geographical Indications and Trade Mark The Register and Conditions for Registration of Geographical Indication Procedure for Registration, Duration of Protection, Rights conferred by Registration, Infringement of Geographical Indications and Remedies. • Introduction to Copyrights: Concept and Principles Historical background and Development of Copyright Law Leading International Instruments, Berne Convention, Universal Copyright Convention, International Copyright under Copyright Act WIPO Phonograms and Performances treaty ,Conditions for grant of copyright, extent of rights exception to copyright protection, fair use provision, assignment and licensing, Copyright in Literary, Dramatic and Musical, Works, Sound Recording, Cinematograph	5

	Films, Copyright in Computer Programme, Author Special Rights, Right of Broadcasting and performers.	
IV	Protection of other types of Intellectual Property Rights in India: ● Protection of other types of Intellectual Property Rights in India: Protection of Plant Varieties and Farmer's Rights in India, Protection of Bio-diversity, Semiconductor Integrated Circuits and Layout Designs ● Introduction Meaning and Scope of traditional Knowledge – Interface between IP and traditional Knowledge, Need and Significance of protection, International instruments on Traditional Knowledge, Developments in WIPO. ● Recognition and Documentation of Traditional Knowledge Databases: Traditional Knowledge Digital Library "TKDL" – AYUSH Systems of Medicines – Biodiversity Register. ● Statutory Protection of Traditional knowledge in India Traditional Knowledge as Property – Nature of Property in genetic Resources and associated traditional Knowledge - Ownership in Traditional Knowledge: Nature and Elements of Ownership – Exclusivity and Protection –Benefit Sharing.	5
V	Procedural Aspects of Patent Registrations and searching ● Procedural Aspects of Patent Registration: Disclosure of Invention, Drafting and Filing the Patent Application Practical aspects of Drafting Patent Application, Procedural aspects in registration of Patent, Procedural Aspects of Trademark, copyright, Design Registration: Registration procedures, requirement of forms, Registration Fee structure. ● Patent Searching: Patent search using different types of patent databases, forming patentability opinion Rights and Obligations of a Patentee, Limitation of rights - Use and exercise of Rights – Right to Secrecy, Compulsory Licenses , Criteria of Infringement – Modes of Infringement (Doctrine of Colourable Variation), Onus of Proof, Defences in suits of Infringement – Injunctions and related remedies.	5
VI	IP Commercialization, Licensing and International aspects of IPR ● IP Commercialization and licensing: Ownership, Assignment, License, Translation of Copyright, Compulsory Licences, Infringement of IP rights, Infringement of Copyright-Films, Literary and Dramatic works, Importation and Infringement. Concept of royalty. IP Valuation basics. ● International aspects of IPR: World Intellectual Property Organisation (WIPO) – Functions of WIPO – Membership – GATT ● Agreement – Major Conventions on IP – Berne Convention – Paris Convention – TRIPS agreement. Requirements under TRIPS, The Hague Agreement, The Geneva Act of Hague Agreement, Classification of Locarno Agreement, The Classification Scheme for trademarks.	5

Learning Resources

Sr. No	References
1	Innovation and Entrepreneurship in Biotechnology – An International Perspective Concepts, Theories and Cases Damian Hine (Senior Lecturer, University of Queensland, Australia) John Kapeleris (Deputy CEO, Australian Institute for Commercialisation, Brisbane, Australia) 2006
2	Building a conducive environment for life science-based entrepreneurship and industry clusters Mark J. Ahn and Michael Meeks, Journal of Commercial Biotechnology. Vol 14. No 1. 20–30 January 2008
3	Report of the Expert Committee on Innovation and Entrepreneurship NITI Aayog, New Delhi, August 2015
4	India is the nesting ground for young entrepreneurs and new start-ups Nikita Agarwal International Journal of Applied Research 2015; 1(7): 578-582
5	National Biotechnology Development Strategy – Promoting bioscience research, education and entrepreneurship Department of Biotechnology, Ministry of Science & Technology, Government of India, 2015
6	Good Incubation In India – Strategies for supporting social enterprise in challenging contexts Madeleine Gabriel, Florence Engasser and Kirsten Bound, January 2016
7	Biotechnology Industry Research Assistance Council : http://www.birac.nic.in
8	Law relating to Intellectual Property Rights, India, IN: Lexis Nexis, Ahuja, V K. (2017).
9	Intellectual Property Rights: Protection and Management. India, IN: Cengage Learning India Private Limited Nithyananda, K V. (2019).
10	Subramanian, N., & Sundararaman, M. (2018). Intellectual Property Rights – An Overview. Retrieved from http://www.bdu.ac.in/cells/ipr/docs/ipr-eng-ebook.pdf
11	World Intellectual Property Organisation. (2004). WIPO Intellectual property Handbook. Retrieved from
12	https://www.wipo.int/edocs/pubdocs/en/intproperty/489/wipo_pub_489.pdf

BTH-411	Biotechnology Practicals-11	
	Major-Practical	
	No. of Credits: 2 No. of Hours: 30	
	Course Outcomes (COs) On completion of the course, the students will be able to:	Bloom's Cognitive Level
CO1	State and explain the organization of genome complexity.	1
CO2	Explain genome assembly and their tools.	2
CO3	Describe tools and techniques for genome assembly, annotation and protein sequences by homology-based alignment.	3
CO4	Discuss the various interactions between the genome and proteins.	4
CO5	Outline databases and advanced bioinformatics tools for analysis of whole genomes and proteomes.	5
CO6	Integrate genomics, proteomics and metabolomics for elucidation of pathways.	6

BTH-411: Biotechnology Practicals-11
Major-Practical

Unit. No	Contents	No. of Practicals (15P)
I	Demonstration of concept of genome organization by: a) Isolation of chromatin (determination of mononucleosome structure) b) Isolation of chromosomes and its application in genomics	2
II	Genome assembly: De novo and reference based-assembly, Contigs, Scaffolds, Genome assembly algorithms and tools.	2
III	Genome annotation: functional annotation of predicted genes or protein sequences by homology-based alignment.	3
IV	Isolation of histone and demonstration of 2D-gel electrophoresis	2
V	Proteome analysis tool: MaxQuant, Perseus softwares and KEGG pathway annotations analysis	2
VI	Protein-protein interaction network and Functional enrichment analysis using STRING	2
VII	Human metabolome database: application in metabolomics and biomarker discovery	1
VIII	Visit to a laboratory equipped with sequencing and microarray facilities	1

BTH-412	Biotechnology Practicals-12 Major-Practical	
	No. of Credits: 2 No. of Hours: 30	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's Cognitive Level
CO1	Demonstrate the technique to initiate and maintain primary suspension cultures using aseptic techniques.	1
CO2	Analyze the growth characteristics of mammalian cells by constructing growth curves.	2
CO3	Perform isolation of plant protoplasts and develop haploid plants using anther/pollen culture techniques.	3
CO4	Execute genetic transformation of plant tissues using <i>Agrobacterium rhizogenes</i> .	4
CO5	Estimate and interpret biochemical parameters plants under stress conditions.	5
CO6	Apply biochemical methods to estimate ascorbic acid content in fruits and compare levels in ripe and unripe samples.	6

BTH-412: Biotechnology Practicals-I12
Major-Practical

Unit. No	Contents	No. of Practicals (15P)
	Animal Biotechnology	
I	Initiation of primary suspension culture	2
II	Subculturing and routine maintenance of suspension cell culture	2
III	Study of mammalian cell growth curve and effect of growth factors on cell growth	3
IV	Visit to Tissue Culture laboratory	1
	Plant Biotechnology	
I	Isolation and observation of Protoplasts/Anther or Pollen Culture for production of haploid plants.	2
II	Transformation of plant tissues using <i>Agrobacterium rhizogenes</i> .	2
III	Estimation of Biochemical Parameters in Plants under stress (Eg. Proline, Lipid Peroxidation, Chlorophyll content)	2
IV	Estimation of Ascorbic acid in in ripe and unripe fruits	1

BTH-451	Stem cell, regenerative medicine and cancer biology Major- Theory	
	No. of Credits: 04 No. of Hours: 60	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's cognitive level
CO1	Recall basic concepts of stem cells, potency, and differentiation.	1
CO2	Describe stem cell types, niches, and therapeutic uses.	2
CO3	Demonstrate techniques for stem cell culture and genetic modification.	3
CO4	Examine tissue engineering methods and regenerative therapies.	4
CO5	Critique ethical issues and recent advances in cancer and stem cell research.	5
CO6	Develop strategies for stem cell applications in disease treatment and research.	6

BTH-451: Stem cell, regenerative medicine and cancer biology
Major- Theory

Sr. No	Topic	Total No. of hours (60)
I	Introduction to stem cell biology: • Concept of stemness, cellular basis of differentiation, trans-differentiation, metaplasia and regeneration with respect to stem cells • Potency: concept and mechanisms of self-renewal, cell cycle regulation in stem cells • Stem cell niches: embryonic, adult and Induced Pluripotent Stem Cell niches	8
II	Working with stem cells: • Isolation, expansion, characterization and maintenance of embryonic stem cells, adult stem cells, embryonic germ cells, embryonic carcinoma cells, Toxicity Screening using cell lines Genetic manipulation of stem cells • Overview of different methods of introduction of a viz. micronuclear injection method, transduction with recombinant retroviruses, targeted gene insertion, Cre-loxP recombination and production of transgenic animals. • Mouse models to study human disorders	15
III	Stem Cell Therapy • Ongoing research and engineering of stem cells for use as direct therapeutics: Applications in neurodegenerative disorders, spinal cord injury, wound healing, burns, diabetes, orthopaedic applications, infertility, HIV/AIDS	6

IV	Ethical considerations Theories, limitations, controversies and criticism of stem cell research and therapy	5
V	Introduction to tissue engineering - Overview of <i>in vivo</i> tissue organization, tissue dynamics and homeostasis - Cells as building blocks: types and extraction methods. ECM, cell-cell/ cell-ECM interactions - Scaffolding: concept, different materials used for scaffold synthesis, their advantages and drawbacks - Assembly of engineered tissues: self-assembly, organ printing etc. - Examples of Engineered tissues: tissue engineering of heart valves, bioartificial skin, liver, cartilage etc., artificial meat, - Tissue Engineering Regulations, controversies and market	10
VI	Cancer Biology - Overview and staging of cancer - Tumour development: cancer signalling, angiogenesis, interactions in tumour microenvironment, metastasis and invasion, immune system evasion - Diagnostics and Pathology: molecular profiling, imaging, and histological techniques - Therapeutics: introduction to traditional and emerging molecular therapies, Role of biotechnology in cancer treatment - Research Methods: cancer model systems (in vitro and in vivo) - Cancer epidemiology: genetic predisposition, gene-environment interaction, in Western vs Indian scenario, survey-based case-studies.	16
	Reading of current research publications in all modules.	

Learning Resources

Sr. No	References
1	Lanza, R., Gearhart, J., Hogan, B., Melton, D., Pedersen, R., Thomas, E. D., Thomson, J., & Wilmut, S. (2009). <i>Essentials of stem cell biology</i> (2nd ed.). Academic Press/Elsevier Inc
2	Glick, B. R., Pasternak, J. J., & Patten, C. L. (2010). <i>Molecular biotechnology: Principles and applications of recombinant DNA</i> (4th ed.). ASM Press.
3	Meyer, U., Handschel, J., Wiesmann, H. P., & Meyer, T. (Eds.). (2009). <i>Fundamentals of tissue engineering and regenerative medicine</i> . Springer Berlin Heidelberg.
4	Gilbert, S. F. (2010). <i>Developmental biology</i> (9th ed.). Sinauer Associates.
5	Wolpert, L., Tickle, C., & Martinez Arias, A. (2019). <i>Principles of development</i> (6th ed.). Oxford University Press

6	Alberts, B., Johnson, A., Lewis, J., Morgan, D., Raff, M., Roberts, K., & Walter, P. (2014). <i>Molecular biology of the cell</i> (6th ed.). Garland Science.
7	Lodish, H., Berk, A., Kaiser, C. A., Krieger, M., Bretscher, A., Ploegh, H., Amon, A., & Martin, K. C. (2021). <i>Molecular cell biology</i> (9th ed.). W.H. Freeman and Company.
8	Weinberg, R. A. (2014). <i>The biology of cancer</i> (2nd ed.). Garland Science.
9	Pelengaris, S., & Khan, M. (Eds.). (2013). <i>The molecular biology of cancer: A bridge from bench to bedside</i> (2nd ed.). Wiley-Blackwell.
10	Mahla, Ranjeet Singh. "Stem cells application in regenerative medicine and disease therapeutics". International Journal of Cell Biology, issue. 7, 2016, pp. 1–24. doi:10.1155/2016/6940283. PMC 4969512. PMID 27516776.
11	Rosemann, Achim. "Why regenerative stem cell medicine progresses slower than expected". Journal of Cellular Biochemistry, vol. 115, issue no. 12, December 2014, pp. 2073–76. doi:10.1002/jcb.24894. PMID 25079695.
12	Zhang, Bin; Yeo, Ronne Wee Yeh; Tan, Kok Hian; Lim, Sai Kiang. "Focus on Extracellular Vesicles: Therapeutic Potential of Stem Cell-Derived Extracellular Vesicles". International Journal of Molecular Sciences, vol. 17, issue no. 2, February 2016.
13	https://pubmed.ncbi.nlm.nih.gov/6349488/
14	Screening of toxic compounds in tissue culture. Ekwall B. Toxicology. 1980;17(2):127-42. doi: 10.1016/0300-483x(80)90085-2. PMID: 7209994

BTH-452	Industrial Biotechnology Major- Theory	
	No. of Credits: 04 No. of Hours: 60	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's cognitive level
CO1	Identify key concepts of industrial biotechnology and bioprocessing.	1
CO2	Describe bioreactor systems and large-scale production processes	2
CO3	Apply principles of fermentation, mass transfer, and scale-up to industrial processes	3
CO4	Analyze production systems in microbial, plant, and mammalian biotechnology	4
CO5	Evaluate regulatory standards, QA/QC, and industrial practices.	5
CO6	Develop integrated bioprocess strategies using modern computational tools	6

BTH-452: Industrial Biotechnology**Major- Theory**

Sr. No.	Topic	No. of hours (60)
I	Introduction to Industrial Biotechnology - Definition, Product types, Lay out of a typical Bioprocess pipeline - Current Scenario in Industrial Biotechnology - Biosafety, bioethics and regulatory overview in industrial biotechnology	3
II	Bioreactor systems - Rationale of development of bioreactor design from conventional to current bioreactors - Design and construction of conventional Stirred tank reactor and non- mechanically agitated bioreactors - Animal and Plant Cell Bioreactors - Immobilized cell reactors. - New designs of Bioreactors. - Operational Modes of Bioreactors	5
III	Large scale microbial technology - Industrially important microorganisms, Production Strains (Characteristics) Aeration and Agitation Requirements for Aerobic Fermentations Aeration: Oxygen Transfer and Oxygen Uptake in cultures, Ccrit, Oxygen transfer from gas bubble to Cell, Gas hold up, K_{La} importance, Factors affecting K_{La}. Mass transfer: Concept of mass transfer, Molecular and Convective mass transfer, Two – film theory and role in bioprocess Agitation and Bulk Mixing	12

	● Power requirement for mixing, Power number, Reynolds number, Flow regimes in fermentation tank (Laminar, turbulent and transition), ● Correlation between mass transfer coefficient and operating variables Large Scale Production processes (Upstream and Downstream) of: Yeast and yeast products, Antibiotics, Vaccines, Insulin using microbial cells.	
IV	Large scale plant biotechnology ● Plant cultures as a production platforms and different cell types used ● Large scale genetic transformation systems in plants ● Secondary metabolite production and yield improvement using elicitors ● Plant Cell-based production of biotechnological relevant molecules	7
V	Large scale mammalian biotechnology ● Engineering mammalian cells for improved productivity ● Biologics and biosimilars: methods of production, extraction and applications of antibody drug conjugates, monoclonal antibodies, vaccines, Tissue Plasminogen Activator etc. using animal cell lines	7
VI	Scale Up and Scale Down (For all types of processes)	3
VII	GMP, cGMP, GILSP, Containment Levels, Regulatory aspects, QA /QC	5
VIII	In-Silico and Computational Biotechnology for Industry ● Design of Multi-Epitope Vaccine using Immunoinformatics Approach ● Drug design and discovery approaches: Molecular docking, Virtual screening, Pharmacophore mapping, QSAR, ADMET prediction, Homology modelling, Network Pharmacology, Drug-Target Interaction & Pathway Analysis, use of AI and ML ● Virtual simulation of bioprocesses	12
IX	Integrated Industrial Bioprocessing ● Upstream and downstream integration in industrial bioprocesses ● Using multiple host systems for production ● Case studies of successful biotechnology products and platforms ● Effluent treatment for industrial waste - Case Study ● Future trends: automation and robotics in industries ● Economics of bio-industries ● Overview of other types of bio-industries	6
	Reading of current research publications in all modules.	

Learning Resources

Sr. No	References
1	Stanbury, P. F. and Whittaker, A. and Stephen J Hall ; Principles of Fermentation technology; 3 rd edition (2016), Butterworth Heinemann , Elsevier
2	Pauline M. Doran, Bioprocess Engineering Principles (2 nd Edition) Academic Press, 2013
3	Prescott. S. C. and Dunn, C. G.; Industrial Microbiology, Reed G.; 4th revised edition (2004), CBS
4	Crueger, W. and Crueger, A.; Biotechnology:A TextBook of Industrial Microbiology, (2017) Medtech
5	E. M. T. El-Mansi, Jens Nielsen, David Mousdale, Ross P. Carlson(2019),Fermentation Microbiology and Biotechnology, 4th Edition,CRC press.
6	S.K. Agarwal (2007) Environmental Biotechnology, APH Publishing Co-operation, New Delhi
7	Bioreactor Design and Product Yield (1992), BIOTOL series, Butterworths Heinemann.
8	Butterworth, Heinemann, Operational Modes of Bioreactors, (1992), BIOTOL
9	Aiba, S., Humphrey A. L. and Miles, N.F. Biochemical Engineering, 2 nd Edition , 2015
10	Glick, B. R., Patten, C. L., Pasternak, J. J., & Lloyd, D. (2010). Molecular biotechnology: Principles and applications of recombinant DNA (4th ed.). ASM Press.
11	Slater, A., Scott, N. W., & Fowler, M. R. (2008). Plant biotechnology: The genetic manipulation of plants (2nd ed.). Oxford University Press.
12	Filippi, M., Mekkattu, M., & Katzschnann, R. K. (2025). Sustainable biofabrication: From bioprinting to AI-driven predictive methods. Trends in Biotechnology, 43(2), 290-303. https://doi.org/10.1016/j.tibtech.2024.07.002
13	Smith, H. J., & Williams, H. (2006). Smith and Williams' introduction to the principles of drug design and action (4th ed.). CRC Press.
14	Silverman, R. B., Juncosa, J. I., & Xue, F. (2026). The organic chemistry of drug design and drug action (4th ed.). Elsevier.
15	Roberts, G. C. K. (1977). Drug action at the molecular level. University Park Press. (Original classic edition — later editions are not widely indexed in major catalogs.)
16	Martin, Y. C. (2010). Quantitative drug design: A critical introduction (2nd ed.). CRC Press

BTH-453	Clinical Research and Data Management Elective-Theory	
	No. of Credits: 4 No. of Hours: 60	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's Cognitive Level
CO1	Discuss and analyze the new drug development process and discuss regulatory and ethical requirements.	1
CO2	Design a basic protocol for the conduct of scientific enquiry and the interpretation of the data obtained.	2
CO3	Demonstrate competency in clinical methods, including accurately reporting observations, analysis and understanding clinical management practice.	3
CO4	Specify the principles of Pharmacovigilance and employ the drug regulatory affairs and ethical requirements.	4
CO5	Describe the different clinical data management systems	5
CO6	Demonstrate critical thinking skills to improve employment opportunities and integrate Pharma Regulatory Affairs.	6

**BTH-453: Clinical Research and Data Management
Elective-Theory**

Sr. No	Topic	Total No. of hours (60)
	Clinical Research	30
I	Introduction to Clinical Research: • Clinical Research: An Overview, Different types of Clinical Research. • Clinical Pharmacology: Pharmacokinetics, Pharmacodynamics, Pharmaco epidemiology, Bioavailability. Bioequivalence, Terminologies and definition in Clinical Research. • Drug Development Process: Preclinical trail, Human Pharmacology (Phase-I), Therapeutic Exploratory trail (Phase-II), Therapeutic Confirmatory Trail (Phase-III) and Post marketing surveillance (Phase-IV).	6
II	Guidelines, Regulation and Ethics in Clinical Research: • Brief History of Clinical Research: Sulphanilamide Tragedy, Thalidomide Disaster, Nazi Experiments, Tuskegee Study, Belmont report, Nuremberg code, Declaration of Helsinki principles. • Guidelines in Clinical Research-International Conference on Harmonization (ICH), Guidelines for Good Clinical Practice, ICMR guidelines for Biomedical Research on Human Subjects. • Regulation in Clinical Research- Drug and cosmetic act, FDA, Schedule-Y- Ethics Committee and their responsibilities.	6

	Clinical Research Regulatory Submission & approval Process- IND, NDA and ANDA submission Procedure. DCGI submission procedure. Other Regulatory authorities- EMEA, MHRA, PhRMA.	
III	Clinical Trial Management: - Introduction: Concept of Clinical Trail Management, Stake holders in Clinical Trail project. - Sponsors perspective: Responsibility of Sponsors, Study Preparation Initial Documents and capability assessment, Study feasibility, Vendors/Service provider selection, Investigator selection, Budgeting in Clinical trial, Clinical Trail Agreement(CTA), Regulatory submission and approval, Sponsors obligation in Good Clinical Practice. - Investigator perspective: Investigators obligation outlined in Good Clinical Practice, Recruitment, Retention and Compliance of study subjects, Ethics committee submission, adverse event and safety reporting. - Service provider/Vender perspective: Contract Research Organization (CRO), Site Management Organization (SMO), Central Lab, Clinical Data Management Organization(CDMO), Medical Writing Organization, Logistic Management Organization, Pharmacovigilance Organization.	6
IV	Clinical Research Operations, Monitoring and Clinical Evaluation: - Clinical Research Operation, Monitoring and Clinical Evaluation: Project management, Protocol in Clinical Research, Informed Consent, Case Report Form, Investigator's Brochure (IB). - Selection of an Investigator and Site, Patient screening, Inclusion and exclusion criteria, Randomization, Blinding, Recruitment Techniques (materials and methods) - Retention and complaisance of study subjects, Ethics and Regulatory submission, Monitoring Visits, Investigator Meeting, Essential Document preparation (IB, ICF, PIS, TMF, ISF, CDA.CTA etc).	6
V	Quality Management and International GMP Regulation: - GMP, GLP, QA and QC (Quality Management): International GMP regulation, Indian GMP regulation, Quality assurance in Pharmaceutical Industry, Quality control in Pharmaceutical Laboratory. - GLP principles: Organizational and personal, Quality assurance program, facilities, Equipments, Reagents and Materials, Test systems, Test and Reference Items. Standard Operating Procedure, Performance of study reporting of results, storage of records and reports. - Responsibility of Clinical Research Professionals: Investigator, Project Manager, Regulatory Affairs Associate, Medical Writer, Clinical Research Associate, Clinical Research Coordinator and Safety Report Associate.	6
	Clinical Data Management	30

I	Clinical Data Management Systems: • CDM Systems: Clinical data management systems, , Electronic data capture systems, Choosing vendor products, Implementing new systems, System validation, Test procedures, Change control, Coding dictionaries, Migrating and archiving Legacy Data, • Clinical Data Management Process-Data Management Plan, CRF design considerations, Database design considerations, Study setup, Entering Data, Tracking CRF pages, cleaning data, Managing Lab Data, Identifying and Managing the discrepancies. • Collecting Adverse Event Data, Coding Reported terms, creating report and Transferring data, Closing study, SAS in Clinical data analysis, Importing data from Excel to SAS, Statistical analysis of SAS datasets. Standard operating procedures and guidelines for data management.	15
II	Pharma Regulatory Affairs: • Pharmacovigilance-Safety specification and risk management plan, Drug Hypersensitivity, Guidelines in Pharmacovigilance. • Drug Regulatory Authorities- Drug policy in India, Regulation on alternative system of Medicine, Safety of Herbal medicines, Medical and Scientific writing.	15
	Reading of current research publications in all modules.	

Learning Resources

Sr. No	References
1	Microbial Genetics, Narosa book distributors Pvt. Ltd., New Delhi, Maloy, S.R.; Cronan, Jr., Freifelder D.; 2nd edition (2009).
2	Principles of Genetics, 8th Edn. John Wiley & Sons. Inc. New York. Gardner, Simmons, Snustad. (2006).
3	Genetics-Analysis of genes and genomes, Jones and Bartlett learning; Hartl, D. L., Jones, E. W., 8th Edition, (2011).
4	Principles of genetics, , John Wiley & Sons, Inc., Snustad, Simmons; 6th Edition (2011).
5	Lawrence MF, Curt DF, David LD (2010) Fundamentals of clinical trials Tom Brody (2016). Clinical trials. Elsevier
6	EPIDEMIOLOGY. Elsevier, Leon Gordis (2014). Lawrence MF, Curt DF, David LD (2010) Fundamentals of clinical trials
7	Fundamentals of Statistics, Published by Prentice Hall, 2nd Edition 2; Goon AM, Gupta MK, Dasgupta B (2008).

8	Data Management for Surveys and Trials . A practical premier using epidata. The Epidata Association;Steve B, Mark M, Damien J, Andrzej R (2001).
9	WHO (2002). Handbook for good clinical research practice: Guidance for implementation. WHO Library Cataloguing-in-Publication Data
10	Good Clinical Practice: Standard Operating Procedures for Clinical Researchers. Wiley;Josef K, Paul M, Graeme S (2000).

BTH-454	Food Biotechnology Elective-Theory	
	No. of Credits: 04 No. of Hours: 60	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's cognitive level
CO1	Recall basic concepts of food biotechnology and food classification	1
CO2	Explain food composition, spoilage, and contaminants.	2
CO3	Apply methods for food analysis and safety testing.	3
CO4	Analyze food processing and preservation techniques	4
CO5	Evaluate specialty foods and food safety systems	5
CO6	Design strategies for food preservation and quality control.	6

**BTH-454: Food Biotechnology
Elective-Theory**

Sr. No.	Topic	Total No. of hours (60)
I	Introduction & Classification of Foods - Overview of Food Technology — History, Scope, and Careers - Classification of Foods — Based on Origin & Composition; Processing and Preservation and shelf life	4
II	Food Composition & Analysis of Foods - Functional Components of Foods (Macronutrients & Micronutrients) - Physical, Chemical properties, Characteristics of foods - Proximate analysis - Sensory analysis Food safety analysis: Common Food contaminants and Adulterants: biological (bacteria/viruses), chemical (cleaning agents/pesticides), physical, and allergen contamination, methods of detecting pesticides: gas and liquid chromatography and mass spectroscopy - Antinutrients: phytates, oxalates, phosphates, avidin	15
III	Food spoilage and detection - Chemical, physical and microbial food spoilage - Sources of microbes in food, factors controlling growth of microorganisms - Food poisoning: examples of bacterial and non-bacterial food borne illnesses - Detection of food spoilage: molecular methods	7
IV	Food Processing and preservation Importance of food processing	15

	● Methods of food processing- Blanching, Sterilization, Drying and Dehydration Techniques, Non-thermal Processing ● Methods of food preservation- Temperature controlled preservation- Refrigeration & Freezing, canning & Pasteurization; Chemical preservation, Radiations, emerging non-thermal techniques ● Food packaging- Factors, methods and materials used, Sustainable packaging	
V	Specialty foods: Nutraceuticals, Functional foods, Nutrigenomics ● Definition and Types of Specialty Foods ● Functional Foods – conventional and modified foods ● Nutraceuticals as supplements and remedies in various diseases ● Probiotics and Prebiotics ● Fermented foods ● Single cell proteins, algae and algal proteins ● Impact of nutrition in biology of ageing ● Nutrigenetics, profiling and personalised diets	15
VI	Food legislation and Standards: ● FSSAI and other food safety authorities ● HACCP system ● Concept of QA, QC, ISO.	4

Learning Resources

Sr. No	References
1	deMan, J. M., Finley, J. W., Hurst, W. J., & Lee, C. Y. (2018). <i>Principles of food chemistry</i> (4th ed.). Springer.
2	Jay, J. M., Loessner, M. J., & Golden, D. A. (2020). <i>Modern food microbiology</i> (8th ed.). Springer.
3	Robertson, G. L. (2012). <i>Food packaging: Principles and practice</i> (3rd ed.). CRC Press.
4	Vaclavik, V. A., Christian, E. W., & Campbell, T. (2021). <i>Essentials of food science</i> (5th ed.). Springer.
5	Malik, J. A., Goyal, M. R., & Kumari, A. (Eds.). (2023). <i>Food process engineering and technology: Safety, packaging, nanotechnologies and human health</i> . Springer.
6	Manay, N. S., & Shadaksharaswamy, M. (2024). <i>Food: Facts and principles</i> (4th ed.). New Age International.
7	Vaclavik, V. A., & Christian, E. W. (2025). <i>Handbook of food chemistry</i> (updated ed.). Springer.
8	Bamji MS, Krishnaswamy K, Brahmam GNV (2009). Textbook of Human Nutrition, 3rd ed.: Oxford and IBH Publishing Co. Pvt. Ltd.
9	Fuller, Gordon W, New Product Development from Concept to Marketplace: CRC Press,2004
10	Food Safety and Standards Authority of India portal, Government of India
11	https://www.fda.gov/food/laboratory-methods-food/about-bacteriological-analytical-manual-bam
12	https://www.cdr.wisc.edu/
13	http://www.agr.gc.ca/eng/science-and-innovation/?id=1360882179814
14	https://www.centerforfoodsafety.org/
15	https://www.ifst.org/
16	https://www.who.int/health-topics/food-safety/

BTH-461	Biotechnology Practical-13	
	Number of Credits: 02 No. of Hours: 30	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's cognitive level
CO1	Recall basic cell culture equipment and techniques.	1
CO2	Outline steps involved in primary culture and subculturing.	2
CO3	Carry out cell culture, subculturing, and cytotoxicity assays under aseptic conditions.	3
CO4	Examine and interpret cell growth patterns and assay results.	4
CO5	Assess tissue engineering applications and cancer-related data.	5
CO6	Prepare and present reports based on cancer epidemiological field-work.	6

BTH-461: Biotechnology Practical-13

Unit. No	Contents	No. of Practicals (15P)
I	Initiation of primary cell culture from chick embryo	3
II	Subculture and observation of the cell line established from the chick embryo	3
III	Cytotoxicity analysis of various compound on cells in culture	4
IV	Survey of current tissue engineering application in India	2
V	Survey of cancer prevalence in Indian population	2
VI	Visit to a stem cell facility	1

BTH-462	Biotechnology Practical-14	
	No. of Credits: 02 No. of Hours: 60	
Course Outcomes (COs) On completion of the course, the students will be able to:		Bloom's cognitive level
CO1	Identify and isolate industrially important production strains.	1
CO2	Explain fermentation parameters and sterility requirements.	2
CO3	Perform production and assays for quantification and analysis of microbial and plant products	3
CO4	Analyze growth kinetics, optimization, and scale-up processes.	4
CO5	Evaluate different methods for culture maintenance and storage	5
CO6	Design basic in silico models for docking and vaccine development.	6

BTH-462: Biotechnology Practical-14

Unit. No	Contents	No. of Practicals (15P)
I	Lab Scale to Bench Top Fermentation Process: • Screening and identification (Genus Level) of any one production strain (enzyme /antibiotic / or any other) from a source. • Optimization of different parameters of the isolates (conventional and Statistical design) • Growth rate determination of the production strain • Scale up to Lab Bench Fermenter (Setting up fermenter for production) • Recovery and assay of the product	4
II	Sterility testing of product/substrates and the cells	1
III	Spirulina culture and its biochemical analysis/ Biofuel production by using Algae.	2
IV	Suspension cell culture for plant secondary metabolite production	3
V	Maintenance and storage of industrially relevant cultures	1
VI	Practical Based on Molecular Docking and Simulation	2
VII	<i>In Silico</i> Vaccine Designing	2
VIII	Visit to a bioprocess industry/organisation/laboratory	