

B.Sc. Biotechnology 5th Semester

Program Name	B.Sc. Biotechnology	Semester	5th Semester
Course Title	Plant Biotechnology (Theory + Practical)		
Course Code:	BTC5	No. of Theory Credits	04
Contact hours	60hrs	Duration of ESA/Exam	3 Hours
Formative Assessment Marks	40	Summative Assessment Marks	60

Course Objectives

1. To understand the fundamental aspects of plant tissue culture.
2. Learn about biotechnological tools and techniques used in plant research and agriculture.
3. Explore methods of introducing foreign genes into plants through transformation techniques.
4. Gain practical skills in plant tissue culture for plant improvement and propagation.
5. To understand the concepts of modern technology pertaining to large-scale production of agricultural products and evaluate several methods for stable and transient plant transformation.
6. Design strategies for plant genetic manipulation against biotic and abiotic stressors.
7. Hypothesize strategies to increase plant yield and fruit/seed quality.

Course Outcomes:

After completing this course, the student is expected to learn the following:

1. Demonstrate a comprehensive understanding of plant biology, physiology, genetics, and molecular biology.
2. Apply biotechnological tools and techniques used in plant research and agriculture, such as plant tissue culture, genetic engineering and transgenics.
3. Execute plant tissue culture techniques for callus induction, somatic embryogenesis, and micropropagation, and apply them in plant breeding and propagation.
4. Perform plant transformation methods and demonstrate the ability to introduce foreign genes into plants using different techniques.
5. Utilize molecular markers and genomic approaches for genetic mapping, marker-assisted selection, and plant breeding programs.
6. Apply molecular biology techniques, including PCR, DNA sequencing, and gene expression analysis, to investigate and analyze plant genetic information.
7. Utilize bioinformatics tools and databases to analyze and interpret plant genomic and transcriptomic data.
8. Apply knowledge about ethical considerations and regulatory frameworks associated with plant biotechnology and genetically modified crops.
9. Apply acquired knowledge and problem-solving skills to address real-world challenges in agriculture, food security, and environmental sustainability using plant biotechnology approaches.

Content of Theory	60 hrs
Unit-I – Plant Tissue culture	15
Introduction, history, definition, hypothesis, and concept of totipotency. Principles of plant tissue culture, types of culture, morphogenesis, differentiation, callus, direct and indirect organogenesis. In vitro propagation and micropropagation, Seed culture, embryo culture, bud culture, limitations, applications in horticulture, agriculture, and forestry. Meristem culture, Somaclonal variation. Commercial micropropagation of Banana and Sugarcane. Haploid Production, Anther culture, Pollen culture, Ovary culture, Ovule culture - technique, limitations, and applications. Protoplast culture, Somatic hybridization, cybrids.	
Unit -II <i>In vitro</i> secondary metabolite production	20
Introduction to secondary metabolites, major secondary metabolites, and applications. <i>In vitro</i> secondary metabolite production, Suspension cultures, cell cultures, root cultures, hairy root cultures, growth Vs secondary metabolite production, yield enhancement, elicitation, biotransformation, bioreactors and scaling up of secondary metabolite production, limitations, and applications. Case studies of Shikonin and root cultures of <i>Panax ginseng</i> .	
Unit -III Transgenic Plants	15
Introduction to Transgenic Plants. Overview of transgenic plants and their significance in agriculture. Historical background and development of plant genetic engineering. Benefits and controversies associated with transgenic plants. Transgenic Plant Technology - Techniques for introducing foreign genes into plants: Agrobacterium-mediated transformation, biolistics, and other methods. Selection and screening of transformed plants. Molecular markers and reporter genes used in transgenic plant research. Transgene Integration and Expression. Mechanisms of transgene integration into plant genomes. Factors influencing transgene expression: promoters, enhancers, and regulatory elements. Methods for analyzing and verifying transgene expression. Applications of Transgenic Plants - Improved crop traits through genetic engineering: pest resistance, herbicide tolerance, disease resistance, and abiotic stress tolerance. Case studies of commercially important transgenic crops.	
Unit -IV Biosafety and Regulatory Considerations	10
Safety assessment of transgenic plants: potential risks and benefits. International regulatory frameworks for releasing and commercializing genetically modified organisms (GMOs). Public perception and consumer acceptance of transgenic plants. Ethical considerations of genetic engineering in plants. Socio-economic impacts of transgenic crops on farmers and agricultural systems. Intellectual property rights and access to transgenic technologies. Emerging trends and technologies in plant biotechnology - genome editing (CRISPR-Cas9) and RNA interference (RNAi)	

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz, and Assignments. Case studies highlight successful applications and challenges in transgenic crop development. Group discussion and critical analysis of scientific papers related to transgenic plants.

Summative Assessment = 60 Marks	
Formative Assessment Occasion/ type	Weightage in Marks
Attendance	10
Seminar	10
Debates and Quiz	10

Test	10
Total	60 marks + 40 marks = 100 marks

Course Title	Plant Biotechnology	Practical Credits	2
Course No./ Course Code:	BTC5-P	Contact hours	60 hrs
Content of Practical			
<ol style="list-style-type: none"> Laboratory organization of basic and commercial plant tissue culture Media preparation (MS, B5), solid media preparation, and Liquid media preparation Explant preparation – Leaf, bud, rhizome, and meristem Callus culture- Initiation and establishment of different types of callus cultures Micropropagation – Stage 0, 1, 2, 3, and 4 Acclimatization and hardening techniques Anther culture and pollen culture Ovary and Ovule culture Isolation and culture of Protoplast Staining, cell viability, and cell count of cell cultures Hairy root culture by Agrobacterium rhizogenic transformation 			

Practical Assessment			
Assessment			
Formative Assessment		Summative Assessment	Total Marks
Assessment Occasion/ type	Weightage in Marks	Practical Exams	
Record	05	25	50
Test	10		
Attendance	05		
Performance	05		
Total	25	25	

References
<ol style="list-style-type: none"> Bhojwani, S.S., and Razdan, M.K. (2004). Plant Tissue Culture: Theory and Practice. Amsterdam: Elsevier Science. Brown, T.A. (2010). Gene Cloning and DNA Analysis: An Introduction. 7th edition. Oxford: Wiley-Blackwell. Gardner, E.J., Simmons, M.J., and Snustad, D.P. (2008). Principles of Genetics. 10th edition. Hoboken, NJ: John Wiley & Sons. Glick, B.R., and Pasternak, J.J. (2018). Molecular Biotechnology: Principles and Applications of Recombinant DNA. 5th edition. Washington, DC: ASM Press. Raven, P.H., Johnson, G.B., Losos, J.B., and Singer, S.R. (2013). Biology. 10th edition. New York, NY: McGraw-Hill Education.

6. Reinert, J., and Bajaj, Y.P.S. (1997). Applied and Fundamental Aspects of Plant Cell, Tissue and Organ Culture. Berlin: Springer.
7. Russell, P.J. (2013). iGenetics: A Molecular Approach. 3rd edition. Boston, MA: Benjamin Cummings.
8. Sambrook, J., Fritsch, E.F., and Maniatis, T. (1989). Molecular Cloning: A Laboratory Manual. 2nd edition. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press.
9. Slater, A., Scott, N.W., and Fowler, M.R. (2008). Plant Biotechnology: The Genetic Manipulation of Plants. Oxford: Oxford University Press.
10. Smith, R. (2012). Plant Tissue Culture: Techniques and Experiments. 3rd edition. San Diego, CA: Academic Press.
11. Taiz, L., and Zeiger, E. (2014). Plant Physiology. 5th edition. Sunderland, MA: Sinauer Associates.
12. Vasil, I.K., and Vasil, V. (2007). Molecular Improvement of Cereal Crops. Dordrecht: Springer

B.Sc. Biotechnology 5th Semester

Program Name	B.Sc. Biotechnology	Semester	5th Semester
Course Title	Animal Biotechnology (Theory + Practical)		
Course Code:	BTC5–T	No. of Theory Credits	04
Contact hours	60 hrs	Duration of ESA/Exam	03 Hours
Formative Assessment Marks	40	Summative Assessment Marks	60

Course Objectives:

- Understand principles of animal biology and genetics
- Explore biotechnological techniques in animal research and applications
- Study applications of animal biotechnology in breeding, production, and disease management
- Examine ethical and regulatory considerations
- Apply knowledge to real-world challenges in agriculture, veterinary medicine, conservation, and biomedical research
- Understand the need for animal biotechnology for human welfare.

Course Outcomes:

After completing this course, the student is expected to learn the following:

1. Understand the biology and characterization of cultured cells, including their adhesion, proliferation, differentiation, morphology, and identification.
2. Gain practical skills in basic mammalian cell culture techniques, measuring growth parameters, assessing cell viability, and understanding cytotoxicity.
3. Learn about germplasm conservation techniques and the establishment of gene banks, along with large-scale culture methods for cell lines.
4. Explore organ and histotypic culture techniques, biotransformation, 3D cultures, whole embryo culture, somatic cell cloning, and the ethical considerations surrounding stem cells and their applications.
5. Develop knowledge of the manipulation of animal reproduction, including artificial insemination, embryo transfer, in vitro fertilization, and somatic cell cloning. Understand ethical issues and applications like recombinant vaccines and probiotics for disease

control.

- Understand gene transfer techniques in animals, including vectors, gene constructs, selectable markers, transfection methods, production of transgenic animals, integration and identification of transgenes, and ethical considerations in transgenesis. Stay updated on recent advances and applications.

Content of Theory	60 hrs
Unit-I History and terminology	15
Pluripotency, Differentiation, Reprogramming, Embryonic stem cells (ESCs), Induced pluripotent stem cells (iPSCs), Multipotency, Trans differentiation, Chimera, and gene knockout Biology and characterization of cultured cells- cell adhesion, proliferation, differentiation, morphology of cells, and identification. The basic technique of mammalian cell culture in vitro, Measuring parameters of growth in cultured cells, cell viability, and cytotoxicity. Germplasm conservation and establishment of gene banks. Large-scale culture of cell lines- monolayer, suspension, and immobilized cultures.	
Unit -II Organ and histotypic culture	15
Technique, advantages, limitations, applications. Biotransformation - Induction of cell line mutants and mutations. 3D cultures. Whole embryo culture. Somatic cell hybridization. Stem cells: types (embryonic, adult), isolation, identification, expansion, differentiation and uses, stem cell engineering, ethical issues. Commercial applications of animal tissue culture. Hazards and safety aspects of tissue culture.	
Unit -III	15
Manipulation of animal reproduction and characterization of animal genes, Manipulation of reproduction in animals. Artificial insemination, embryo transfer, and <i>in vitro</i> fertilization. Embryo transfer in cattle and applications. Somatic cell cloning - cloning of Dolly. Ethical issues. Production of recombinant vaccines. Probiotics for disease control.	
Unit - IV Vectors for gene transfer in animals	15
Retrovirus, Gene constructs promoter/ enhancer sequences for transgene expression in animals. Selectable markers for animal cells- thymidine kinase, dihydrofolate reductase, CAT. Transfection of animal cells- calcium phosphate coprecipitation, electroporation, lipofection, peptides, direct DNA transfer, viral vectors, microinjection. Methods for producing transgenic animals- retroviral, microinjection, engineered stem cell. Targeted gene transfer. Transgene integration and identification methods. Transgenic and genome-edited animals. Ethical issues in transgenesis. Recent advances and applications in the field.	

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz and Assignments

Summative Assessment = 60 Marks	
Formative Assessment Occasion/ type	Weightage in Marks
Attendance	10
Seminar	10
Debates and Quiz	10
Test	10

Total	60 marks + 40 marks = 100 marks
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Course Title	Animal Biotechnology	Practical Credits	02
Course No./ Course Code:	BTC5–P	Contact hours	60 hrs

Content of Practical

1. Preparation of cell culture media: Preparation of basic cell culture media, such as Dulbecco's Modified Eagle Medium (DMEM), supplemented with fetal bovine serum (FBS), antibiotics, and other required additives.
2. Aseptic techniques and sterile handling: Practicing aseptic techniques, including properly handling tools and equipment, working in a laminar flow hood, and maintaining sterility throughout the cell culture process.
3. Filter sterilization: Practice filter sterilization for sensitive media ingredients.
4. Cell counting and viability assessment: Count cells using a hemocytometer or automated cell counter, and perform viability assays (e.g., trypan blue exclusion) to determine the percentage of viable cells.
5. Cell passaging and subculturing: Practicing subculturing cells by passaging them from one culture vessel to another, following proper techniques for detachment, trypsinization, and seeding at appropriate densities.
6. Cell freezing and thawing: Learn or demo the cryopreservation process by freezing and thawing cells using cryoprotective agents and controlled cooling and thawing rates.
7. Cell staining and microscopy: Staining the cultured cells using dyes such as hematoxylin and eosin (H&E), and observe them under a light microscope to study cell morphology and structure.
8. Contamination identification and troubleshooting: Learn to identify and troubleshoot common issues in cell culture, such as contamination by bacteria, fungi, or mycoplasma, and implement appropriate corrective measures.
9. Cytotoxicity assays: Students can assess the cytotoxic effects of substances (e.g., drugs, chemicals) on cultured cells using assays like the MTT or LDH assay.
10. Experimental design and data analysis: Students can design and execute simple experiments, record and analyze data, and interpret the results based on their observations and measurements.

Practical Assessment

Assessment

Formative Assessment		Summative Assessment	Total Marks
Assessment Occasion/ type	Weightage in Marks	Practical Exams	
Record	05	25	50
Test	10		
Attendance	05		
Performance	05		
Total	25	25	

References

1. Wilson, K., & Walker, J. (2018). Principles and Techniques of Biochemistry and Molecular Biology (8th ed.). Cambridge University Press. ISBN: 978-1316614761.
2. Gahlawat, S.K., Duhan, J.S., Salar, R.K., Siwach, P., Kumar, S., & Kaur, P. (2018). Advances in Animal Biotechnology and its Applications. Springer. ISBN: 978-981-10-4701-5.
3. Primrose, S.B., & Twyman, R.M. (2016). Principles of Gene Manipulation (8th ed.). Blackwell Science. ISBN: 978-1405135442.
4. Verma, A., & Singh, A. (2013). Animal Biotechnology. Elsevier. ISBN: 978-0124160026.
5. Glick, B.R., & Pasternak, J.J. (2009). Molecular Biotechnology (4th ed.). ASM Press. ISBN: 978-1555814984.
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9. Masters, J.R.W. (Ed.). (2000). Animal Cell Culture - Practical Approach. Oxford University Press.
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11. Pörtner, R. (Ed.). (2007). Animal Cell Biotechnology: Methods and Protocols. Humana Press.
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13. Gupta, P.K. (2018). Animal Biotechnology. Rastogi Publications.
14. Mather, J.P., & Barnes, D. (Eds.). (Year N/A). Animal Cell Culture Methods. In Methods in Cell Biology, Vol. 57. Academic Press.
15. Singh, B.D. (2006). Biotechnology: Expanding Horizons (3rd ed.). Kalyani Publishers.
16. Srivastava A.K. Animal Biotechnology. (2018). Oxford & IBH Publishing Co Pvt. Ltd, 458pp.

B.Sc. Biotechnology 5th Semester

Program Name	B.Sc. Biotechnology		Semester	5 th Semester
Course Title	Genetic Engineering (Theory + Practical)			
Course Code:	BTC5-T	No. of Theory Credits		04
Contact hours	60hrs	Duration of ESA/Exam		03 Hours
Formative Assessment Marks	40	Summative Assessment Marks		60

Course Objectives

1. Understand the fundamental principles and techniques of genetic engineering.
2. Explore the applications of genetic engineering in agriculture, medicine, biotechnology, and environmental science.
3. Develop practical skills in genetic engineering techniques and laboratory procedures.
4. Gain knowledge of gene expression regulation and genetic modification methods.
5. Analyze and interpret genetic data using bioinformatics tools.

6. Enhance critical thinking and problem-solving skills through discussions and case studies.
7. Stay updated on emerging trends and advancements in genetic engineering.

Course Outcomes:

1. Demonstrate a thorough understanding of the fundamental principles and techniques of genetic engineering.
2. Apply the knowledge of genetic engineering to diverse applications in agriculture, medicine, biotechnology, and environmental science.
3. Perform laboratory procedures and develop practical skills in genetic engineering techniques. CO4: Explain gene expression regulation mechanisms and apply genetic modification methods effectively.
4. Analyse and interpret genetic data using bioinformatics tools for a comprehensive understanding of gene function and evolutionary relationships.
5. Evaluate genetic engineering's ethical, social, and legal implications and propose responsible solutions.
6. Stay updated with recent advancements in genetic engineering, critically evaluate emerging trends, and assess their potential impact on various fields.

Content of Theory	60 hrs
Unit I- Fundamentals of Genetic Engineering	15
<p>Introduction to Genetic Engineering - Definition, scope, and historical overview of genetic engineering. Importance and applications in various fields.</p> <p>DNA Structure and Manipulation - Structure and organization of DNA molecules. Techniques for DNA isolation and purification. Methods for quantification and characterization of DNA samples.</p> <p>RNA Analysis and Gene Expression- Types and functions of RNA molecules. Methods for RNA isolation and purification. Analysis of gene expression using techniques such as Northern hybridization. Introduction to Polymerase Chain Reaction (PCR) and its variants for gene expression analysis</p> <p>Recombinant DNA technology – Introduction to molecular cloning. Overview of cloning vectors. Plasmids, phage, cosmid, BAC, and YAC. Features and applications of cloning vectors in genetic engineering. Enzymes used in recombinant DNA technology: Restriction endonucleases, DNA modifying enzymes, other nucleases, Polymerases, Ligase, kinases, and phosphatases. Techniques for molecular cloning of DNA or RNA fragments in bacterial and eukaryotic systems.</p>	
Unit II- Practices in Genetic Engineering	15
<p>Unit 2: Techniques - Protein Expression and Purification. Techniques for expressing recombinant proteins using bacterial, animal, and plant expression systems. Strategies for protein purification and characterization</p> <p>Gene Manipulation Techniques - Methods of gene delivery. Physical, chemical, and biological methods. transformation, transfection, electroporation, and micro-injection. Gene knockout techniques in bacterial and eukaryotic organisms.</p> <p>Genome Editing - Introduction to genome editing techniques- Principles and applications of genome editing techniques. CRISPR-Cas9, site-directed mutagenesis, and other genome editing methods.</p>	

Ethical and Regulatory Considerations - Discussion of ethical implications associated with genetic engineering. Introduction to regulatory guidelines and safety considerations for genetic engineering research and applications

Unit III- Applications of Genetic Engineering	15
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Introduction to Applications. Overview of the diverse applications of genetic engineering. Gene therapy and its potential in treating genetic disorders. Strategies for gene delivery in therapeutic applications. Diagnostic Applications. DNA fingerprinting and its applications in forensics. Molecular diagnostic techniques and their role in disease diagnosis. Use of genetic engineering in the development of therapeutics and vaccines. Production of biopharmaceuticals using recombinant DNA technology.

Crop Improvement and Biotechnology in Agriculture. Genetic engineering for crop improvement, including enhanced traits and disease resistance. The role of biotechnology in sustainable agriculture.

Unit IV- Advances in Genetic Engineering	15
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Industrial Applications. Industrial applications of genetic engineering, such as enzyme production, biofuel production, and bioremediation. Scale-up techniques and process optimization in industrial settings. Introduction to synthetic biology and its integration with genetic engineering. Design and construction of artificial biological systems

Bioinformatics and Computational Tools. Introduction to bioinformatics and its role in genetic engineering. Use of computational tools for sequence analysis, gene prediction, and protein structure analysis.

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz and Assignments

Summative Assessment = 60 Marks	
Formative Assessment Occasion/ type	Weightage in Marks
Attendance	10
Seminar	10
Debates and Quiz	10
Test	10
Total	60 marks + 40 marks = 100 marks

Course Title	Genetic Engineering	Practical Credits	02
Course No./ Course Code:	BTC5-P	Contact hours	60 hrs
Practical			

1. **Introduction to Laboratory Techniques** - Safety guidelines and laboratory protocols
Aseptic techniques and proper handling of materials. Basic equipment and instrument operation
Preparation of reagents and media
2. **Nucleic Acid Extraction and Quantification**- DNA extraction from different sources (e.g., bacteria, plant, animal). RNA extraction and purification methods. Quality assessment and quantification of nucleic acids (spectrophotometry, gel electrophoresis).
3. **Polymerase Chain Reaction (PCR)**
Primer design and optimization
PCR setup and cycling conditions
Agarose gel electrophoresis for PCR product analysis
4. **Cloning and Plasmid Manipulation**
Restriction enzyme digestion and ligation reactions
Transformation of bacterial cells with recombinant plasmids
Colony selection and screening for successful cloning
5. **Protein Expression and Purification**
Selection of expression system (e.g., bacterial, yeast, insect cells)
Plasmid construction for protein expression
Protein expression induction and optimization
Protein purification techniques (e.g., affinity chromatography, gel filtration)
6. **Gel Electrophoresis and DNA Analysis**
Agarose gel electrophoresis for DNA fragment separation and analysis
DNA size determination using molecular weight markers
DNA band visualization techniques (e.g., ethidium bromide staining, DNA intercalating dyes)
7. **Gene Knockdown and RNA Interference (RNAi)**
Design and synthesis of small interfering RNA (siRNA)
Transfection of siRNA into cells for gene knockdown
Evaluation of gene knockdown efficiency (e.g., qPCR, Western blot)
8. **Genome Editing Techniques**
Introduction to the CRISPR-Cas9 system and its applications
Design of guide RNA (gRNA) for target gene editing
Transfection of CRISPR-Cas9 components into cells
Analysis of genome editing efficiency (e.g., T7 endonuclease I assay, Sanger sequencing)
9. **Bioinformatics for Genetic Engineering**
Introduction to bioinformatics databases and tools
Sequence analysis (e.g., BLAST, multiple sequence alignment)
Prediction of protein structure and function

Practical Assessment

Assessment

Formative Assessment		Summative Assessment	Total Marks
Assessment Occasion/ type	Weightage in Marks	Practical Exams	
Record	05	25	50
Test	10		
Attendance	05		
Performance	05		
Total	25	25	

References

1. Principles of Gene Manipulation and Genomics (2016) 8th ed., Primrose, SB, and Twyman, R, Wiley Blackwell, ISBN: 978-1405156660.
2. Gene Cloning and DNA Analysis: An Introduction (2019) 7th ed., Brown, TA, Wiley Blackwell, ISBN: 978-1119072560.
3. Genome 4 (2017) 4th ed., Brown, TA, Garland Science, ISBN: 978-0815345084.
4. Introduction to Genomics (2015) 2nd ed., Lesk, AM, Oxford University Press India, ISBN: 978-0198745891.
5. Genomics and Personalized Medicine: What Everyone Needs to Know (2016) 1st ed., Snyder, M, OUP-USA, ISBN: 978-0190234768.
6. Molecular Biology of the Gene (2014) 7th ed., Watson, JD, Baker, TA, Bell, SP, Gann, A, Levine, M, and Losick, R, Pearson, ISBN: 978-0321762436.
7. Principles of Gene Manipulation and Genomics (2019) 9th ed., Primrose, SB, and Twyman, R, Wiley Blackwell, ISBN: 978-1119163774.
8. Genomes (2018) 4th ed., Brown, TA, Garland Science, ISBN: 978-0815345084.
9. Introduction to Genomics and Proteomics (2015) 2nd ed., Burrell, MM, Wiley, ISBN: 978-0470850075.
10. Genomics: The Science and Technology Behind the Human Genome Project (2019) 2nd ed., Gibson, G, and Muse, SV, Oxford University Press, ISBN: 978-0198786207.
11. Genomics and Evolution of Microbial Eukaryotes (2019) 1st ed., Katz, LA, and Bhattacharya, D, Oxford University Press, ISBN: 978-0198830202.
12. Essentials of Genomic and Personalized Medicine (2016) 2nd ed., Ginsburg, GS, and Willard, HF, Academic Press, ISBN: 978-0124078652.
13. Genomic Medicine: Principles and Practice (2014) 2nd ed., Ginsburg, GS, and Willard, HF, Oxford University Press, ISBN: 978-0199334468.
14. Genomic Medicine in Resource-limited Countries: Genomics for Every Nation (2019) 1st ed., Wonkam, A, Puck, JM, and Marshall, CR, Academic Press, ISBN: 978-0128133003.
15. Molecular Genetics and Genomics (2020) 1st ed., Krebs, JE, and Goldstein, ES, Jones & Bartlett Learning, ISBN: 978-1284154544.
16. Bioinformatics and Functional Genomics (2015) 3rd ed., Pevsner, J, Wiley-Blackwell, ISBN: 978-1118581780.
17. Genomic Approaches for Cross-Species Extrapolation in Toxicology (2019) 1st ed., Wichard, J, and Maertens, A, CRC Press, ISBN: 978-0815348023.
18. Introduction to Genetic Analysis (2020) 12th ed., Griffiths, AJF, Wessler, SR, Carroll, SB, and Doebley, J, W.H. Freeman, ISBN: 978-1319149609.
19. Genetic Engineering: Principles and Methods (2019) 3rd ed., Fowler, MR, CABI, ISBN: 978-1789240605.

B.Sc. Biotechnology 5th Semester

Program Name	B.Sc. Biotechnology	Semester	5th Semester
Course Title	Environmental Biotechnology (Theory)		
Course Code:	BTC5–T	No. of Theory Credits	03
Contact hours	60hrs	Duration of ESA/Exam	03 Hours
Formative Assessment Marks	35	Summative Assessment Marks	40

Course Objectives:

1. Understand the fundamental concepts and principles of environmental biotechnology and Explore the interrelationship between biotechnology and the environment.
2. Gain knowledge of the various applications of biotechnology in environmental conservation, pollution control, and sustainability.
3. Develop an understanding of the key techniques and methodologies used in environmental biotechnology research and applications.
4. Learn about microbial processes and their role in environmental biotechnology.
5. Understand the principles of bioremediation and its application in the clean-up of environmental pollutants.
6. Explore the potential of bioenergy production and waste management through biotechnological approaches.
7. Identify and characterize the most important contaminants in the Bioprocess and other industrial wastes.
8. Analyze the effect of different contaminant on different bioprocess and in analytical techniques.
9. Bioreactor performance in biological treatment of different contaminants.
10. Reuse/recycle the biological waste to clean technology such as energy, biofuel, bio fertilizer through bioremediation

Course out comes:

1. Demonstrate a comprehensive understanding of the fundamental concepts and principles of environmental biotechnology.
2. Apply knowledge of biotechnological techniques to address environmental challenges, such as pollution control and waste management.
3. Analyze and evaluate environmental biotechnology case studies, research findings, and real-world applications.
4. Design and implement biotechnological approaches for environmental remediation, utilizing microbial processes and biodegradation principles.
5. Evaluate the ethical and sustainable aspects of environmental biotechnology practices and make informed decisions regarding their application in environmental conservation.
6. Communicate scientific concepts and research findings related to environmental biotechnology effectively, both in written and oral forms, to diverse audiences.

Content of Theory	60 hrs
Unit I- Fundamentals of Environmental Biotechnology	15
<p>Introduction to Environmental Biotechnology- Principles of Environmental Science. Role of Biotechnology in Environmental Conservation. Microbial Processes in Environmental Biotechnology.</p> <p>Pollution and Biotechnology - Major issues in environmental pollution and the role of biotechnology in addressing them. Biotechnological Methods of Pollution Detection-General bioassay methods for pollution detection. Cell biological methods for assessing pollution levels. Immunoassays for detecting specific pollutants. DNA-based methods for pollution identification. Use of biosensors in pollution monitoring. Biotechnological Methods in Pollution Abatement-Reduction of CO₂ emission using biotechnological approaches. Conventional wastewater treatment methods. Utilizing algae for wastewater treatment. Bioreactors for advanced wastewater treatment. Addressing eutrophication through biotechnological interventions. Application of cell immobilization techniques in pollution abatement.</p>	
Unit II- Definition and principles of bioremediation	15
<p>Importance of bioremediation in environmental cleanup. Types of contaminants suitable for bioremediation. Factors influencing bioremediation efficiency. Role of microorganisms in bioremediation processes. Types of microorganisms used in bioremediation (bacteria, fungi, algae). Metabolic pathways involved in contaminant degradation Genetic engineering and bioaugmentation in enhancing microbial capabilities. In-situ Bioremediation Methods. Bioaugmentation. Biostimulation. Bioventing. Phytoremediation. Ex-situ Bioremediation Methods- Composting, Landfarming, Biopile and bioslurry systems. Xenobiotics. Environmental Monitoring and Assessment. Importance of monitoring during bioremediation processes. Sampling techniques and analysis of contaminants. Assessment of microbial activity and degradation effectiveness. Long-term monitoring and post-remediation assessment.</p>	
Unit III- Wastewater Treatment and Management	15
<p>Introduction to Wastewater Management. Wastewater Characterization and Composition. Biological Processes in Wastewater Treatment. Activated Sludge Process and Biological Nutrient Removal Anaerobic Digestion and Biogas Production from Wastewater. Membrane Bioreactors and Advanced Biological Treatment Technologies. Bioremediation of Contaminated Wastewater. Emerging Biotechnologies for Wastewater Treatment. Sustainable Approaches in Wastewater Management Case Studies and Innovations in Wastewater Biotechnology.</p>	
Unit IV- Solid Waste Management	15
<p>Introduction to Solid Waste Management. Solid Waste Characterization and Classification. Biotechnology Applications in Solid Waste Management. Composting and Vermicomposting Techniques for Organic Waste Recycling and Waste Minimization Strategies. Bioenergy Production from Organic Waste Bioplastics and Bio-based Materials in Solid Waste Management. Hazardous Waste Management and Biotechnological Solutions. Technological Innovations in Solid Waste Biotechnology. Case Studies and Success Stories in Solid Waste Management. Bio metallurgy and bio-mining</p>	

Reference Books

1. Peavy, H. S., Rowe, D. R., & Tchobanoglous, G. (2014). Environmental engineering. McGraw-Hill Education.
2. Banerjee, S., & Santhosh, C. (2019). Environmental biotechnology: Concepts and applications. CRC Press.

3. Mishra, A. K. (2016). Environmental biotechnology: Basic concepts and applications. CRC Press.
4. Torres, A. E., & López-González, J. A. (2018). Environmental biotechnology: An introduction. John Wiley & Sons.
5. Das, S., & Dash, H. R. (2020). Environmental biotechnology: Principles and applications. Springer.
6. Wackett, L. P., & Hershberger, C. D. (2018). Environmental biotechnology: Theory and application. McGraw-Hill Education.
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9. Ignacimuthu S. (2001). Basic Biotechnology. Rev. Fr. Tata McGraw Hill, New Delhi,
10. Ratledge C. and Kristiansen B. (2002). Basic Biotechnology. Cambridge University Press, UK.

Program Name	B.Sc. Biotechnology	Semester	5th Semester
Course Title	Biotechnology Skills and Analytical Techniques		
Course No.	VOC- I	No. of Theory Credits	2+1 (Theory+ Practical)
Contact hours	45 hrs	Duration of ESA/Exam	2hrs
Formative Assessment Marks/ Practical Component	20	Summative Assessment Marks	30

Course Outcomes (COs): At the end of the course the student should be able to:

1. Demonstrate skills as per National Occupational Standards (NOS) of the “Lab Technician/Assistant” Qualification Pack issued by the Life Sciences Sector Skill Development Council-LFS/Q0509.
2. Develop knowledge of laboratory safety procedures and protocols and acquire skills in handling and maintaining laboratory equipment and instruments.
3. Operate analytical equipment and instruments as per standard operating procedures (SOP)
4. Knowledge about major activities of the biotech industry, regulations and compliance, environment, health and safety (EHS), good laboratory practices (GLP), and Good Manufacturing Practices (GMP) as per the industry standards.
5. Demonstrate soft skills, such as decision-making, planning, organizing, problem-solving, analytical thinking, critical thinking, and documentation.

Course Articulation Matrix: Mapping of Course Outcomes (COs) with Program Outcomes (POs 1-13)

Course Outcomes (COs)/Program Outcomes (POs)	1	2	3	4	5	6	7	8	9	10	11	12	13
Develop knowledge of laboratory safety procedures and protocols and acquire skills in handling and maintaining laboratory equipment and instruments.	✓	✓											
Operate analytical equipment and instruments as per standard operating procedures (SOP)		✓	✓									✓	
Knowledge about major activities of the biotech industry, regulations and compliance, environment, health and safety (EHS), good laboratory practices (GLP), and Good Manufacturing Practices (GMP) as per the industry standards.		✓							✓		✓		
Demonstrate soft skills, such as decision making, planning, organizing, problem solving, analytical thinking, critical thinking and documentation.	✓	✓						✓	✓				

Program Name	B.Sc. Biotechnology	Semester	5th Semester
Course Title	Biotechnology Skills and Analytical Techniques		
Course No.	VOC- I	No. of Theory Credits	2+1 (Theory+ Practical)
Contact hours	45 hrs	Duration of ESA/Exam	02hrs
Formative Assessment Marks/ Practical Component	20	Summative Assessment Marks	30

Content	Total 30 Hrs
Unit-I Insights into the biotechnology industry and basic professional skills	15 Hrs
<p>Biotechnology Industry in Indian and Global Context- Organization in the context of large/medium/small enterprises, their structure, and benefits.</p> <p>Industry-oriented professional skills: Planning and organizing skills, decision-making, problem-solving skills, analytical thinking, critical thinking, team management, and risk assessment. Interpersonal skills: Writing skills, reading skills, oral communication, conflict resolution techniques, interpretation of research data, and troubleshooting in the workplace.</p> <p>Digital skills: Basic computer skills (MS Office, excel, power point, internet) for the workplace. Professional E-mail drafting skills and PowerPoint presentation skills. Overview of good manufacturing practices (GMP), Good Documentation practices (GDP), and good laboratory practices (GLP).</p>	
Unit- II Basic laboratory skills and Analytical Techniques	15 Hrs
<p>Analytical skills in the laboratory: Preparations of solutions, molarity, molality, normality, mass percent % (w/w), percent by volume (% v/v), parts per million (ppm), parts per billion (ppb), dilution of concentrated solutions. Standard solutions, stock solution, and solution of acids. Reagent bottle label reading and precautions.</p> <p>Analytical techniques: Basic principle, operation, application, maintenance, calibration, validation, and troubleshooting of instruments- Microscope-Simple, compound, TEM, SEM, fluorescence. Centrifuge and different types, Hot air oven, pH meter, different types of pH electrodes Autoclave, pH meter, Incubator, BOD, COD, cell counter, Laminar airflow. Spectroscopy-Colorimeter, UV-Visible spectroscopy. Electrophoresis- Agarose Gel electrophoresis, SDS-PAGE, PCR, Conductivity meter, and Potentiometer. Biosafety cabinets.</p>	

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz, and Assignments

Course title	Quality control methods in biology (Practical)	Practical credits	5th Semester
Course No.	VOC -1	Contact hours	4hrs/week 25Marks
Content			
Unit-1			
<p>Methods and practices of cleaning and management of lab: Learning and Practice of Integrated clean-in-place (CIP) and sterilize-in-place (SIP) as per industry standards, material requirements for cleaning specific areas, equipment, ventilation area, personal protective requirements Calibration of and use of micropipette.</p>			

Unit-2
<p>Preparation of Standard Operating Procedure (SOP) for various equipment in the QC Lab, Best practices of using and storing chemicals: Knowledge and practice in handling chemicals, labelling, and stock maintenance. SOP and material handling. Procedures to maintain chemicals, labelling, storage, and disposal.</p> <p>Handling and calibration of lab equipment- weighing balance, Autoclave, Hot air Oven, Incubator, Centrifuge, Water bath, Colony Counter, and stability chamber, Preparation of Normality, Molarity, and buffer solutions</p>
Unit-3
<p>Preparation of media: Maintenance and storage of purified water for media (plant tissue culture media, microbiological media, and animal cell culture media) preparation. Preparation and storage of concentrated stock solutions. Documentation and disposal of expired stocks. Collection of indents of media requirement, preparation, and storage. Media coding, documentation, and purpose of usage.</p> <p>Demonstration, handling, and troubleshooting of High-Performance Liquid Chromatography and Gas chromatography.</p> <p>Demonstration of Polymerase Chain Reaction (PCR), Hands-on training on colorimeter and spectrophotometer, Industry visit, or analytical laboratory visit.</p>

Note: Semester end examination is only in the theory component; questions from the practical part could be included, if any.

References:

1. Douglas A. Skoog, F. James Holler, and Stanley R. Crouch (2017). "Principles of Instrumental Analysis". Cengage Learning.
2. J. Perry Gustafson (2017). "Analytical Methods and Techniques for Advanced Sciences". CRC Press.
3. Dean F. Martin, William M. Ritchey, and Michael W. Wood (2017). "Laboratory Manual for Principles of General Chemistry". Wiley.
4. Michael Lufaso (2016). "Laboratory Skills for Science and Medicine: An Introduction". CRC Press.
5. David J. Livingstone and Christopher H. Amonette (2016). "Analytical Techniques in Environmental Chemistry: Applications to Air, Water and Soil". CRC Press.
6. Colin A. Ramsden (2014). "Analytical Molecular Biology". Oxford University Press.
7. John M. Walker and Ralph Rapley (2014). "Molecular Biomethods Handbook". Humana Press.
8. Gary D. Christian, Purnendu K. Dasgupta, and Kevin A. Schug (2013). "Analytical Chemistry". Wiley.
9. Roger L. Lundblad and Fiona M. Macdonald (2010). "Handbook of Biochemistry and Molecular Biology". CRC Press.

Program Name	B.Sc. Biotechnology	Semester	5^h Semester
Course Title	Skills in Bioinformatics		

Course No.	VOC- 2	No. of Theory Credits	2+1 (Theory+ Practical)
Contact hours	45 hrs	Duration of ESA/Exam	02hrs
Formative Assessment Marks/ Practical Component	20	Summative Assessment Marks	30

Course Outcomes (COs): At the end of the course the student should be able to:

1. Demonstrate skills as per National Occupational Standards (NOS) of “Bioinformatics Associate/Analyst” Qualification Pack issued by Life Sciences Sector Skill Development Council- LFS/Q3102, Level 4
2. Students will become proficient in using various bioinformatics tools like sequence alignment, genome assembly, and databases commonly used in the field of Biotechnology
3. Students will develop skills in analyzing and interpreting biological data generated through high-throughput technologies.
4. Students will develop skills in analyzing and interpreting biological data generated through high-throughput technologies, perform statistical analysis, data mining, and visualization techniques to extract meaningful insights from complex biological datasets and communicate effectively and collaborate in a multidisciplinary bioinformatics environment.

Course Articulation Matrix: Mapping of Course Outcomes (COs) with Program Outcomes (POs 1-13)

Course Outcomes (COs)/ Program Outcomes (POs)	1	2	3	4	5	6	7	8	9	10	11	12	13
Students will become proficient in using various bioinformatics tools like sequence alignment, genome assembly, and databases commonly used in the field of Biotechnology						✓	✓						
Students will develop skills in analyzing and interpreting biological data generated through high-throughput technologies.							✓	✓					
Students will develop skills in analyzing and interpreting biological data generated through high-throughput technologies, perform statistical analysis, data mining, and visualization techniques to extract meaningful insights from complex biological datasets and communicate effectively and collaborate in a multidisciplinary bioinformatics environment.						✓	✓	✓					

Program Name	B.Sc. Biotechnology	Semester	5th Semester
Course Title	Bioinformatics Associate/Analyst		
Course No.	VOC- 2	No. of Theory Credits	2+1 (Theory+ Practical)

Contact hours	45 hrs	Duration of ESA/Exam	02hrs
Formative Assessment Marks/ Practical component	20	Summative Assessment Marks	30

Content	Total 30 Hrs
Unit-I Essentials of Bioinformatics	15 Hrs
<p>Introduction, Overview of bioinformatics and its applications in biology and medicine Introduction to biological databases and data formats. Bioinformatics Database search engines – Text-based search engines (Entrez, DBGET / LinkDB). Sequence file formats: Various file formats for bio-molecular sequences: GenBank, FASTA, GCG, MSF etc. Sequence Analysis: Sequence databases and retrieval methods, Basics of sequence analysis and sequence alignment algorithms, pairwise sequence alignment techniques (e.g., Needleman-Wunsch, Smith-Waterman), Multiple sequence alignment algorithms (e.g., ClustalW, MUSCLE), Sequence similarity searching (e.g., BLAST, FASTA). Basics of Object-Oriented Programming like (C++ / JAVA), JavaScript, R and Python / Perl, and operating system like Linux. Genome Database- Plant genome database- Plant GDB, Microbial Genomes database: -MBGD, Viral genome database:-ICTVdb Practical applications: Case studies and projects illustrating the application of bioinformatics in genomics, personalized medicine, or other relevant areas</p>	
Unit- II Structural Bioinformatics, Molecular Modelling and Drug Designing	15 Hrs
<p>Introduction to Structural Bioinformatics, Protein Structure Prediction: Introduction to protein structure and its importance, Prediction of protein secondary structure and tertiary structure. Protein structure visualization tools. Motif and Domain: Motif databases and analysis tools. Domain databases (CDD, SMART, ProDom) and Analysis tools Introduction to protein-ligand interactions and drug discovery. Analysing Molecular Surfaces, cavities, and intermolecular interaction. Gene Expression Analysis: Introduction to gene expression data analysis, Pre-processing and normalization of gene expression data. Ethical considerations in bioinformatics research. Communication and collaboration in a bioinformatics team</p>	

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz and Assignments

Course title	Bioinformatics Associate/Analyst (Practical)	Practical credits	1 25 Marks
Course No.	VOC -2	Contact hours	4hrs/week
Content			
<ol style="list-style-type: none"> 1. Use of different biological databases and Bioinformatics search engines (e.g., PubMed, UniProt) 2. Retrieval of DNA and protein sequences from online databases. 3. Analysis of sequence properties such as length, GC content and amino acid composition 4. Performing sequence similarity searches using tools like BLAST 5. Aligning multiple DNA or protein sequences using tools like ClustalW or MUSCLE. 6. Analysis of gene structure using ORFfinder, GenScan 7. Identifying conserved regions or motifs within the alignment 8. Analyzing molecular interactions, intra and inter molecular interactions, salt bridges and crystal contacts. 9. Predicting genes within a DNA sequence using tools like GeneMark or Glimmer 10. Evaluation and visualization of 3D structure of biomolecules using open source resources 			

11. Constructing phylogenetic trees using methods like neighbor-joining or maximum likelihood and interpreting and visualizing the tree to understand evolutionary patterns
12. Understanding of Kyoto Encyclopedia of Genes and Genome (KEGG) database for biological pathways, metabolism, cellular process, genetic information processing.
13. Visualization of gene expression patterns through heatmap

Note: Semester end examination is only in the theory component and questions from the practical part could be included, if any.

References:

1. David W. Mount (2021). "Bioinformatics: Sequence and Genome Analysis". Cold Spring Harbor Laboratory Press.
2. Andreas D. Baxevanis and B. F. Francis Ouellette (2018). "Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins". Wiley.
3. Jonathan Pevsner (2015). "Bioinformatics and Functional Genomics". Wiley.
4. Arthur M. Lesk (2014). "Introduction to Bioinformatics". Oxford University Press.
5. Stephen Misener and Stephen A. Krawetz (Editors) (2013). "Bioinformatics: Methods and Protocols". Publisher: Humana Press.
6. Zahoor Ahmad and S. Mohan Jain (Editors) (2012). "Bioinformatics: Concepts, Skills, and Applications". Springer.
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B.Sc. Biotechnology 6th Semester

Program Name	B.Sc. Biotechnology		Semester	6th Semester
Course Title	Medical Biotechnology (Theory + Practical)			
Course Code:	BTC6	No. of Theory Credits	04	
Contact hours	60hrs	Duration of ESA/Exam	03 Hours	
Formative Assessment Marks	40	Summative Assessment Marks	60	

Course Objectives

1. To understand the basic aspects of medical biotechnology, pathogenesis of human diseases, disease diagnosis, management, drug discovery, development and Clinical research.
2. To provide an overview of genetic diseases and the diagnostic techniques used in the medical field.
3. This course focuses on the relationship between microbes and human health. Students will study important diseases emphasizing on etiology, pathogenesis, diagnosis, treatment, and prevention.

Course Outcomes:

After completing this course, the student is expected to learn the following:

1. Understanding the basics of genetic information responsible for disease development
2. Understanding the classical and advanced methods used for the diagnosis of various diseases
3. Students will have a clear understanding of microbial diseases, host pathogen interactions, and the issues associated with drug-resistant microorganisms.
4. Students also comprehend the significance of normal flora associated with human health.
5. They will also learn about drug- Receptor interactions, drug toxicology and its pharmacological significance, conducting clinical trials, ethical issues in clinical research and a preliminary idea about artificial intelligence and personalized medicine as highly emerging areas in medical science.

Content of Theory	60 hrs.
Unit I - INTRODUCTION, MICROBIAL DISEASES & DIAGNOSTICS	15hrs
<p>Medical Biotechnology: Scope and Importance.</p> <p>Microbial diseases in humans: Mode of infection, symptoms, epidemiology and control measures of diseases caused by Viruses (AIDS, Hepatitis-B, Rabies) Bacteria (Typhoid, Cholera, TB, Plague), Fungi (Aspergillosis, Histoplasmosis), Protozoa (Malaria, Amoebiasis).</p> <p>Diagnostics: Applications of immunological and molecular diagnostic methods (RIA, ELISA, PCR, and DNA fingerprinting) in forensic science and disease diagnosis. Clinical proteomics - protein microarray for disease diagnosis. Ethics in molecular diagnosis.</p>	
Unit II- CLINICAL RESEARCH AND NANOBIO TECHNOLOGY	15hrs

<p>Introduction to clinical research, history of clinical research, and an overview. Importance of Indian and global clinical research, Regulatory agencies. Scope of clinical research. ICH-GCP- History, objectives, structure, guidelines, and future of ICH. Different phases of clinical research. Ethical Issues in clinical research- Introduction, codes, declaration, and guidelines.</p> <p>Nanobiotechnology: Preparation of nanomaterials: Mechanical methods (Grinding – high energy ball milling), Physical Methods (Vapor deposition - pulsed laser deposition), Chemical methods (Sol-gel process, Combustion route), Green synthesis (plant and microbial extracts).</p> <p>Applications of nanotechnology: Nano biosensors, Bioremediation, drug and gene delivery, Biochips- analytical devices, disease diagnostics, and cancer therapy Risk potential of nonmaterial.</p>	
Unit III – STEM CELLS AND CANCER BIOLOGY	15hrs
<p>Stem cells: Scope, embryonic and adult stem cells, properties, identification, stem cell culture, techniques and their applications in modern clinical sciences, Cancer stem cells, tissue engineering, and regenerative medicine.</p> <p>Cancer Biology: Tumors, types of tumors, pre-disposing factors, cellular changes involved in tumor formation, genes associated with cancer (oncogenes and tumor suppressor genes), methods of tumor detection, tumor markers, treatment of cancer-chemo therapy, radiotherapy, immunotherapy, and gene therapy.</p>	
Unit IV- VACCINOLOGY	15hrs
<p>History of Vaccinology, conventional approaches to vaccine development, live attenuated and killed vaccines, adjuvants, quality control, preservation and monitoring of microorganisms in seed lot systems.</p> <p>Introduction to newer vaccine approaches namely- subunit vaccines, synthetic vaccines, DNA vaccines, virus-like particles, recombinant vaccines, plantibodies, edible vaccines, Cancer vaccines, nanoparticles in vaccine delivery systems, benefits, and limitations.</p>	

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz and Assignments

Summative Assessment = 60 Marks	
Formative Assessment Occasion/ type	Weightage in Marks
Attendance	10
Seminar	10
Debates and Quiz	10
Test	10
Total	60 marks + 40 marks = 100 marks

Course Title	Medical Biotechnology	Practical Credits	2
Course No./ Course Code:	BTC6	Contact hours	60 hrs
Content of Practical			
1. Bacteriological examination of blood and pus from clinical samples 2. Separation of mononuclear cells by Ficoll hypaque method 3. Haemoglobin estimation using a haemometer 4. Haemagglutination test - Blood Typing 5. Commercial kits-based diagnosis - Widal test, VDRL test 6. Kirby Bauer's Antibiotic Sensitivity test (bacterial) 7. Molecular genotyping of Human Papilloma Virus using PCR technique 8. Liver Functioning tests – Serum albumin and Serum bilirubin tests 9. Cytological examination of normal and tumorous cells 10. Estimation of serum cholesterol 11. Blood glucose estimation by folin wu method			

Practical Assessment			
Assessment			
Formative Assessment		Summative Assessment	Total Marks
Assessment Occasion/ type	Weightage in Marks	Practical Exams	
Record	05	25	50
Test	10		
Attendance	05		
Performance	05		
Total	25	25	

References
1. Robbins S.L. (1974) Pathological basis of Disease. W B Saunders Company 2. Guyton A.C. and Hall J.E. (2006) Textbook of Medical Physiology 11 th edn. Saunders 3. Hage D S and Carr J D, (2010) Analytical Chemistry & Quantitative Analysis, Prentice Hall 4. Brant W.E. and Helms C.A. (2007) Fundamentals of Diagnostic Radiology, 3 rd edn. Lippincott Williams &Wilkins. 5. Glick B. R. and Pasternak J. J. 1994 “Molecular Biotechnology Principles” 6. Jogd and S N. Medical Biotechnology 2nd Edition Himalaya publishers 2008 7. Strayer L. Biochemistry 4th Ed. (1995) W.H. Freeman Co., San Francisco, U.S.A. 8. Vishal Bansal Parar, Clinical Research Fundamental and Practice, Medical Publisher, 2010. 9. Jaypee brothers. Basic Principles of Clinical Research and Methodology, Medical Publishers (P) Ltd., 2009. 10. Gupta, S.K. Basic Principles of Clinical Research and Methodology, 1st edition,2009. 11. Richard B Silverman, Organic Chemistry of Drug Design and Drug action Elsevier Science,

Academic Press.2014.

12. Friedman LM, Furberg CD, DeMets DL, Reboussin DM, Granger CB. Fundamentals of Clinical trials, Springer Nature, Switzerland AG, 2015.

B.Sc. Biotechnology Sixth Semester

Program Name	B.Sc. Biotechnology	Semester	6th Semester
Course Title	Immunology (Theory + Practical)		
Course Code:	BTC6	No. of Theory Credits	04
Contact hours	60 hrs	Duration of ESA/Exam	3 Hours
Formative Assessment Marks	40	Summative Assessment Marks	60

Course Objectives:

1. To understand the various aspects of immunity, elicitation of immune responses, factors determining the outcome of immune responses and major players of immunity, relevance between nutritional support and immunity, and immunological techniques.
2. To provide knowledge on essential features of antigens and antibodies and their types and different theories of Antibody formation.
3. To acquire knowledge on types of immunity, phagocytosis, interferons, and the complement system.
4. To explain the concept of hypersensitivity, autoimmunity, and transplantation.
5. To provide knowledge on immune deficiencies and several immunological techniques

Course Outcomes:

At the end of the course, the student should be able to:

1. Demonstrate comprehension of the underlying structure and function of the immune system and related disorders.
2. Demonstrate an understanding of the role of cells and molecules in immune reactions and responses
3. Demonstrate technical skills in immunological tools and techniques
4. Apply the domain-specific knowledge and skills acquired in immunology for innovative therapies and Immunotechnologies
5. Understand the fundamental concepts of immunity, and the contributions of the organs and cells in immune responses.
6. Realize how the MHC molecule's function and host encounters an immune insult.
7. Understand the antibodies and complement system
8. Understand the mechanisms involved in the initiation of specific immune responses
9. Differentiate the humoral and cell-mediated immune mechanisms
10. Comprehend the overreaction by our immune system leading to hypersensitive conditions and its

consequences

11. Understand unique properties of cancer cells, immune recognition of tumors, immune evasion of cancers

Content of Theory		60 Hrs
Unit-I Cells and Organs of the Immune System		15
<p>Introduction to the Immune System: History of Immunology, Clonal Selection Theory. Defense against pathogenic organisms – viruses, bacteria, fungi.</p> <p>Types of Immunity: first and second line of defense, innate and acquired/adaptive immunity, specificity, diversity, Self and non-self-recognition.</p> <p>Cells of the immune system: Antigen-presenting cells (APCs), Role of B and T-lymphocytes in Humoral immunity and cell-mediated immunity, primary and secondary immune response, Immunization, memory.</p> <p>Organs of the Immune system: Thymus, bone marrow, spleen, Lymph Node, peripheral lymphoid organs</p>		
Unit -II Molecules of the Immune System		15
<p>Antigens and haptens: Properties (foreignness, molecular size, heterogeneity). Adjuvants. Antigenicity and Immunogenicity. Affinity and Avidity. B and T cell epitopes, superantigens</p> <p>Immunoglobulins: Classification, structure, and function. Monoclonal and polyclonal antibodies. VDJ Gene Segments and DNA rearrangements.</p> <p>Major histocompatibility complexes: Classification, structure, and function. Antigen processing pathways – Cytosolic and Endocytic</p> <p>Cytokines: Classification and function</p> <p>Complement: Pathways</p>		
Unit -III Antigen-Antibody Reactions and Immunotechniques		15
<p>Structure and properties of antigens- iso- and allo-antigens, antigen specificity, haptens, and adjuvants. Biomolecular association, Cross-reactivity, Precipitation, Immunodiffusion reactions: Radial immunodiffusion, Ouchterlony double diffusion, Immunoelectrophoresis. Agglutination: Agglutination reactions. ELISA, ELISpot Assay, RIA. Immunocytochemistry, Fluorescent Techniques, FACS. Hybridoma Technology</p>		
Unit - IV		15
<p>Vaccines: Conventional, peptide vaccines, subunit, DNA vaccines. Toxoids, antisera, edible vaccines, plantibodies, ISCOMs, recombinant antibodies, and Cancer vaccines.</p> <p>Transplantation immunology: Phases in graft rejection and immuno-suppressors.</p> <p>Hypersensitivity: Reactions – Types I, II, and III. Delayed Type Hypersensitive Response.</p> <p>Autoimmune Disorders: Systemic and Organ-specific Autoimmune disorders with examples</p> <p>Immunodeficiencies: Primary and secondary immunodeficiencies; acquired immunodeficiency syndrome</p> <p>Cancer and the immune system – immune surveillance, immunological escape, cancer antigens, cancer immunotherapy</p>		

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz and Assignments

Summative Assessment = 60 Marks	
Formative Assessment Occasion/ type	Weightage in Marks
Attendance	10
Seminar	10
Debates and Quiz	10
Test	10
Total	60 marks + 40 marks = 100 marks

Course Title	Immunology	Practical Credits	02
Course No.	BTC6	Contact hours	60 hrs
Content of Practical			
<ol style="list-style-type: none"> 1. Hemagglutination of ABO Blood groups 2. Determination of Rh factor 3. Whole Count of WBC using Hemocytometer 4. Cells of the Immune System 5. Radial immunodiffusion 6. Ouchterlony double diffusion 7. ELISA – Demonstrate 8. Serum Immunoelectrophoresis 9. Western Blotting 			

Practical Assessment			
Assessment			
Formative Assessment		Summative Assessment	Total Marks
Assessment Occasion/ type	Weightage in Marks	Practical Exams	
Record	05	25	50
Test	10		
Attendance	05		
Performance	05		
Total	25		

References
<ol style="list-style-type: none"> 1. Textbook of Immunology, Paul Ajoy, Books and Allied (P) Ltd., 2016 2. Kuby Immunology. Kindt T.J. et al., W.H. Freeman & Co. 2018 3. Cellular and Molecular Immunology. Abbas, A.K. et al., Elsevier Saunders Co., 2015 4. Essential Immunology. Riott, I.M., Blackwell Scientific Publications, 1994 5. Handbook of Experimental Immunology, Vol. 1 & 2, Weir D.M., Wiley, 1997 6. Immunology. Riott, I.M., Brostoff J., Male, D. Mosby Pub., 2017 7. Immunobiology. Janeway C.A. and Travers, P. Churchill Livingstone Pub., 2016 8. Practical Immunology. Hudson L. and Hay F.C., Blackwell Scientific Pub., 1989

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B.Sc. Biotechnology Sixth Semester

Program Name	B.Sc. Biotechnology		Semester	6th Semester
Course Title	Bioprocess Technology (Theory + Practical)			
Course Code:	BTC6	No. of Theory Credits	04	
Contact hours	60hrs	Duration of ESA/Exam	3 Hours	
Formative Assessment Marks	40	Summative Assessment Marks	60	

Course Objectives:

1. The objective of this paper is to introduce students to the fundamentals of bioprocess engineering and technology, and its industrial applications, thus enabling the students to understand the requirements of bioprocess technology in advanced and emerging areas of biological science.
2. The field of biotechnology is developing very rapidly and needs skilled engineers with a bioprocess engineering background to design, build, control, and operate bioreactors and fermenters.
3. Design bioreactors for the production of various products.
4. Analyze and formulate mechanisms for enzymatic reactions.
5. Understand soluble and immobilized enzyme technologies for the production of industrial and medical products.
6. Predict important yield coefficients using the principles of stoichiometry and energetics of microbial growth.
7. Perform simulations of microbial growth and metabolism.
8. Present knowledge about major metabolic pathways and those related to biofuel production from microbes.
9. Analyze metabolic network and metabolic flux.
10. Estimate kinetic parameters from raw fermentation data.
11. Specify required technologies to effectively utilize genetically engineered microorganisms for bioprocessing.

Course outcome:

At the end of the course, the student should be able to:

1. Students can understand the exploitation of microorganisms for industrial use and their improvement, stoichiometric analysis, and formulation of media for efficient growth and production of microbial or cell-based products.
2. Students will also have an idea about the design, operation, and specific applications of various bioreactors.
3. Graduates acquire professional leadership roles in bioprocess engineering and related fields leading to successful career.
4. Graduates establish commitment and contribute toward sustainable and bio-based economic development for a better society.
5. Graduates engage in lifelong learning by conducting practical engineering tasks.
6. Able to acquire a sound knowledge in mathematics and natural science and apply engineering principles in determining and solving contemporary and complex problems related to bioprocessing. Able to formulate and operate conversion processes of biological resources into bio-based value-added materials related to food, feed, fuels,

- pharmaceutical, nutraceutical, biomaterials, or biochemicals.
7. Able to design biological reactions and reactors including their materials, instrumentation, control, and modeling.
 8. Able to communicate a creative idea and works effectively within the professional community and larger society.
 9. Able to demonstrate an ability to work in multidisciplinary and multicultural teams in developing innovative engineering solutions using complex problem-solving skills.
 10. Able to conduct practice-based tasks related to bioprocessing in a responsible, safe, voluntary, self-motivated, and ethical manner.
 11. Able to appraise bioprocessing and bioproducts manufacturing and valorization using entrepreneurship principles

Content of Theory	60 hrs.
UNIT- I Introduction to bioprocess technology. Range of bioprocess technology and its chronological development. Basic principle components of fermentation technology. development and strain improvement of industrially important microorganisms. Types of microbial culture and its growth kinetics– Batch, Fed-batch, and Continuous culture.	10hrs
UNIT- II Design of bioprocess vessels- Significance of Impeller, Baffles, Sparger; Specialized bioreactors- design and their functions: airlift bioreactor, tubular bioreactors, membrane bioreactors, tower bioreactors, fluidized bed reactor, packed bed reactors and photobioreactors Principles of upstream processing – Media preparation, Inocula development, and sterilization.	20hrs
UNIT- III Introduction to oxygen requirement in bioprocess; mass transfer coefficient; factors affecting KLa. Bioprocess measurement and control system with special reference to computer-aided process control.	15hrs
UNIT-IV cell disruption, precipitation methods, solid-liquid separation, liquid-liquid extraction, filtration, centrifugation, chromatography, drying devices (Lyophilization and spray dry technology), crystallization, biosensors-construction and applications, Effluent treatment. Microbial production of ethanol, amylase, lactic acid, and Single Cell Proteins.	15hrs

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz and Assignments

Summative Assessment = 60 Marks	
Formative Assessment Occasion/ type	Weightage in Marks
Attendance	10
Seminar	10
Debates and Quiz	10
Test	10
Total	60 marks + 40 marks = 100 marks

Course Title	Bioprocess Technology	Practical Credits	02
Course No.	BTC6	Contact hours	60 hrs

Content of Practical			
<ol style="list-style-type: none"> 1. Bacterial growth curve. 2. Calculation of the thermal death point (TDP) of a microbial sample. 3. Study of fermentor- Demonstration. 4. Production of wine–estimation of the percentage of alcohol, total acidity & volatile acidity in wine. 5. Production and analysis of ethanol. 6. Production and analysis of amylase. 7. Production and analysis of lactic acid. 8. Isolation of industrially important microorganisms from natural resources. 			

Practical Assessment			
Assessment			
Formative Assessment		Summative Assessment	Total Marks
Assessment Occasion/ type	Weightage in Marks	Practical Exams	
Record	05	25	50
Test	10		
Attendance	05		
Performance	05		
Total	25	25	

References
<ol style="list-style-type: none"> 1. Casida LE. (1991). Industrial Microbiology. 1st edition. Wiley Eastern Limited. 2. Crueger W and Crueger A. (2000). Biotechnology: A textbook of Industrial Microbiology. 2nd edition. Panima Publishing Co. New Delhi. 3. Patel AH. (1996). Industrial Microbiology. 1st edition, Macmillan India Limited. 4. Stanbury PF, Whitaker A and Hall SJ. (2006). Principles of Fermentation Technology. 2nd edition, Elsevier Science Ltd. 5. Colin Ratledge and Bjorn Kristiansen, Basic Biotechnology (3rd Edn.).2022 6. Cambridge University Press. 2002. 7. Jackson AT., Bioprocess Engineering in Biotechnology, Prentice Hall, Engelwood Cliffs, 1991. 8. Mansi EMTEL, Bryle CFA. Fermentation Microbiology and Biotechnology, (2nd Ed). Taylor & Francis Ltd, UK, 2007. 9. Michael, L. Shulers and Fikret Kargi. Bioprocess Engineering: Basic concepts (2nd Ed.) Prientice Hall Publishers. 2001. 10. Paulins, M. D. Bioprocess Engineering Principles. John Wiley Publishers.2003. 11. Prentice Hall, Engelwood Cliffs, 2002. 12. Prescott, Sc and Dunn, C. Industrial Microbiology, McGraw Hill, New York. 1984. 13. Shuler ML and Kargi F., Bioprocess Engineering: Basic concepts, 2nd Edition,

B.Sc. Biotechnology 6th Semester

Program Name	B.Sc. Biotechnology	Semester	6th Semester
Course Title	Medicinal Plant Biotechnology (Theory)		
Course Code:	BTC6-T	No. of Theory Credits	03
Contact hours	60hrs	Duration of ESA/Exam	03 Hours
Formative Assessment Marks	35	Summative Assessment Marks	40

Course Objectives:

1. The topics are designed to help the students to get exposed to various techniques of plant tissue culture.
2. Use biotechnological techniques for obtaining and improving the Quality of natural products/medicinal plants
3. To know the elementary treatment of various morphological, anatomical, and biochemical parameters used in the identification and utilization of medicinal plants in general.
4. To provide an overview of ethnobotany, methods of herbal preparation, tribal medicine, and their importance in present-day drug research.
5. This course will be helpful for students from various science disciplines to explore the application of medicinal values of herbs.
6. Enable the students to understand the phytochemistry and uses of common medicinal herbs

Course out comes:

1. Students will gain the knowledge about various strategies of plant tissue culture and students will gain knowledge about various secondary metabolites produced by plant tissue culture
2. Understand the basic principles of traditional system of herbal medicine
3. Obtain the knowledge on basics of plant diseases and their control measures using herbal plants
4. Explain technical aspects of plant biomolecules
5. Describe the basics of parasitic diseases and their herbal control measures
6. Summarize various forms of human diseases and their treatments using herbal plants
7. Asses the significance of antioxidants, food and herbs to prevent and control diabetes, cancer and cardiac arrest.

Content of Theory	60 hrs
Unit I- Introduction	15
Plants, genes, genomes, epigenomes, and Biotechnology; Plants as sources of medicines; The engineering of medicinal plants: Prospects and limitations, Genetic transformation and production of transgenic plants, Pathway engineering and combinatorial biosynthesis, Bioprocessing, Plant propagation, Phytochemistry. Metabolomics: Introduction, analytical methods, chromatography, GC, HPLC, Capillary electrophoresis, TLC, Spectroscopy, MS, NMR spectrometry, Identification of metabolites.	
Unit II - Plant-associated microorganisms (Endophytes) as sources of bioactive natural products	15
Endophyte diversity, selection of plants, isolation, preservation, and storage of endophytes; fermentation media composition and conditions, use of precursors and elicitors, scale up, examples of bioactive natural products from endophytes.	
Unit III- DNA profiles of plants:	15
Methodology of plant DNA profiling, DNA sequencing, and multilocus DNA profiles – Hybridization-based RFLP fingerprinting, PCR with arbitrary primers, PCR with microsatellites – complementary primers, AFLP analysis; Locus-specific microsatellite DNA markers; PCR-based RFLP analysis of organellar and nuclear genomes; other DNA markers. Application of molecular markers in herbal drug technology. Applications – Genotype identification, plant species, plant cultivars, and accessions, <i>in vitro</i> propagated plant material; Genetic diversity – variation and relatedness, amount and distribution of variability in wild-growing plants, plant systematics; Gene tagging.	
Unit IV- Bioprospecting	15
The search for bioactive, assay systems; lead structures from nature, Secondary metabolites - modes of action and utilization in medicine. Biotechnological approaches for the production of promising plant-based chemotherapeutics, cell cultures, immobilization, feeding precursors, elicitors, <i>in-situ</i> product removal, biotransformation, bioreactor and scale-up, biosynthetic pathway mapping, and metabolic engineering. Biosynthesis of podophyllotoxin, paclitaxel, and camptothecin. Engineered plants: Heterologous expression of plant natural product genes and pathways. Eg. Alkaloids, isoprenoids, sesquiterpenes and diterpenes, Taxol, artemisinin, carotenoids, flavonoids; Production of therapeutic antibodies in plants, protein folding, assembly and glycosylation, downstream processing, biosafety concerns, regulatory issues, ethical and patent issues.	

Reference Books

1. Handbook of Medicinal and Aromatic Plants by S.K. Bhattacharjee (2004).
2. Recent Progress in Medicinal Plants Vol.12, Globalization of Herbal Health by A.K. Sharma (2006).
3. Handbook of Ayurvedic Medicinal Plants by L.D. Kapoor (2005).
4. Indian Medicinal Plants (Vol 1- 4) by K.R. Kirtikar and B.D. Basu (2006).

5. Indigenous Medicinal Plants Social Forestry & Tribals by M.P. Singh et al. (2003).
6. Ayurvedic Drugs and their Plant Sources by V.V. Sivarajan & I. Balachandran, Oxford & IBH (1994).
7. Agro techniques of High Altitude Medicinal and Aromatic Plants by M.C. Nautiyal and B.P. Nautiyal (2004).
8. Medicinal Plants Cultivation: A Scientific Approach by S.S. Purohit (2004).
9. Direct uses of medicinal plants and their identification by Vardhana, Sarup and Sons, Ansari Road, Dariyaganj, New Delhi (2008).
10. Medicinal Plant Biotechnology. Beauchamp J. W., 2011 CBS HB; First Edition
11. Medicinal Plant Biotechnology. Ciddi Veeresham. CBS Publishers & Distributors, 2008
12. Kalsi, P. S. and Jagtap, S., 2012. Pharmaceutical medicinal and natural product chemistry. N.K. Mehra for Narosa Publishing House Pvt. Ltd. New Delhi.
13. Roseline, A. 2011. Pharmacognosy. MJP Publishers, Chennai.
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16. P. C. Trivedi. 2006. Medicinal plants – Traditional knowledge. I.K. International publishinghomo Pvt. Ltd

B.Sc. Biotechnology Sixth Semester

Program Name	B.Sc. Biotechnology	Semester	6th Semester
Course Title	Elements of Process Development and Technology Transfer		
Course No.	VOC- I	No. of Theory Credits	2+1 (Theory+ Practical)
Contact hours	45 hrs	Duration of ESA/Exam	02hrs
Formative Assessment Marks/ Practical Component	20	Summative Assessment Marks	30

Course Outcomes (COs)

At the end of the course, the student should be able to:

1. Demonstrate skills as per National Occupational Standards (NOS) of “Research Associate- Technology Transfer/Process Development- Qualification Pack issued by Life Sciences Sector Skill Development Council-LFS/Q0511, Level 5
2. Gain a comprehensive understanding of principles, concepts, and methodologies related to technology transfer and process development in biotechnology.
3. The course cultivates students' ability to think critically and solve complex problems related to technology transfer and process development in biotechnology.
4. Students acquire knowledge about quality assurance, Good Manufacturing Practices (GMP), and regulatory compliance considerations necessary for successful technology transfer.

Course Articulation Matrix: Mapping of Course Outcomes (COs) with Program Outcomes (POs 1-13)

Course Outcomes (COs)/Program Outcomes (POs)	1	2	3	4	5	6	7	8	9	10	11	12	13
Gain comprehensive understanding of principles, concepts, and methodologies related to technology transfer and process development in biotechnology.	✓				✓							✓	
The course cultivates students' ability to think critically and solve complex problems related to technology transfer and process development in biotechnology.								✓		✓			
Students acquire knowledge about quality assurance, Good Manufacturing Practices (GMP), and regulatory compliance considerations necessary for successful technology transfer									✓		✓		

Program Name	B.Sc. Biotechnology	Semester	6th Semester
Course Title	Elements of Process Development and Technology Transfer		
Course No.	VOC- I	No. of Theory Credits	2+1 (Theory+ Practical)
Contact hours	45 hrs	Duration of ESA/Exam	2hrs
Formative Assessment Marks/ Practical Component	20	Summative Assessment Marks	30

Course Outcomes (COs):	
At the end of the course, the student should be able to:	
<ol style="list-style-type: none"> 1. Gain a comprehensive understanding of principles, concepts, and methodologies related to technology transfer and process development in biotechnology. 2. The course cultivates students' ability to think critically and solve complex problems related to technology transfer and process development in biotechnology. 3. Students acquire knowledge about quality assurance, Good Manufacturing Practices (GMP), and regulatory compliance considerations necessary for successful technology transfer. 	
Content	Total 30 Hrs
Unit-I Essentials of technology transfer and process development	15 Hrs
Process development - Manufacturing new product, GLP and GMP, pilot vs. manufacturing scale, standardized protocols, quality, efficiency & robustness of the processes, raw materials, product life cycle, technical reasons for manufacturing defects, Uni-variant/Multi-variant Design of experiments Essential parameters - Identification/ verification of CPPs and CQAs and other important parameters,	

SOPs, and protocols, Scale-Up and Post-Approval Change (SUPAC) guidelines, FDA guidelines, validation requirements/strategy; Technology transfer - need and relevance, ideal technology transfer	
Unit- II Research planning, documentation, and reporting	15 Hrs
<p>Research planning – resource, time, timeline & budget considerations, and technical feasibility analysis on the NPD ideas by analysing current development plans, and planning day-to-day activities. Research communications - preparation of progress reports/ research outcomes for steering groups/ bodies, principal investigator, communication with upstream and downstream teams</p> <p>Research initiatives – use new areas of research, techniques, and methods, extend research/ product portfolio, creative analysis & interpretation of research data. Decision making – collaborative, appropriate, optimum & best possible solution, Troubleshoot & Resolve problems to avoid delays.</p> <p>Reporting – different standard reference materials used like drugs, products, side effects, adverse reactions, process details, and statistical analysis of test data. Documentation – methods, and procedures of writing and maintaining the lab, research records, research performance reports, schemes and guidelines, power point presentations, tables, charts, word documents, development of research objectives and proposal writing for funding and contractual purposes, publications, and technical writing, Regulatory compliance of the final documents</p>	

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz and Assignments

Course title	Elements of Process Development and Technology Transfer (Practical)	Practical credits	1
Course No.	VOC -1	Contact hours: 15hrs	4hrs/week
Content			
<ol style="list-style-type: none"> 1. Documentation on Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) applied in process development 2. Elements of designing New Process Development (NPD) 3. Preparation of manual for Technology transfer 4. Analysing real-world technology transfer in the pharma and biotech industry through a case study 5. Group projects to develop technology transfer 6. Basic processes and techniques in Biotechnology 7. Technology transfer steps from research to commercialization 8. Survey on emerging markets and globalization technology transfer in industry 9. Basics of process scale-up and risk assessment 10. Demonstration about cell line development and optimization of cell culture conditions 11. Basics of design of experiments and statistical analysis. 			

Note: Semester end examination is only in the theory component and questions from the practical part could be included, if any.

References:

1. Rathore, A. S., & Winkle, H. (2021). Process Validation in Manufacturing of Biopharmaceuticals: Guidelines, Current Practices, and Industrial Case Studies. Wiley.
2. B. Nagarani, (2021), Industrial Pharmacy, Blue Rose Publishers
3. Sinha, S., & Chatterjee, A. (2020). Technology Transfer in Pharmaceutical Manufacturing: Quality and Regulatory Considerations. CRC Press.
4. DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2019). Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. JAMA internal medicine, 179(3), 389-391.
5. Tattam, B. N. (2018). Pharmaceutical Process Validation: An International Third Edition (Drugs and the Pharmaceutical Sciences). CRC Press.
6. Sheikha Al Akhzami (2018), Technology Transfer and commercialization, Daya publishing house.
7. Shah, V. P., & Maibach, H. I. (2017). Topical Drug Bioavailability, Bioequivalence, and Penetration. Springer.
8. Rathore, A. S. (2016). Quality by Design for Biopharmaceuticals: Principles and Case Studies. Wiley.
9. Muzzio, F. J., & Maury, M. (2015). Pharmaceutical Process Scale-Up (Drugs and the Pharmaceutical Sciences). CRC Press.
10. Hussain, A., Wong, M., & Braatz, R. D. (2014). Pharmaceutical Manufacturing Handbook: Regulations and Quality. Wiley
11. Phyllis L. Speser, (2012), The Art and Science of Technology Transfer, Wiley
12. Ian Ernest Cooke, Paul Mayes, (1996), Introduction to innovation and technology transfer, Atech house.
13. Richard D. Robinson, (1988), The international transfer of Technology- Theory, Issues and Practice, Ballinger

Program Name	B.Sc. Biotechnology	Semester	6th Semester
Course Title	Product Development		
Course No.	VOC- II	No. of Theory Credits	2+1 (Theory+ Practical)
Contact hours	45 hrs	Duration of ESA/Exam	02hrs
Formative Assessment Marks/ Practical component	15	Summative Assessment Marks	35

Course Outcomes (COs):

At the end of the course, the student should be able to:

1. Demonstrate skills as per National Occupational Standards (NOS) of “Research Associate- Product Development/ Synthesis/ Medicinal Chemistry” Qualification Pack issued by Life Sciences Sector Skill Development Council-LFS/Q0505, Level 5
2. Understand the fundamental concepts and stages of the product development process.
3. Analyse and mitigate risks associated with product development.
4. Understand ethical considerations in product development and consumer safety case studies to develop their skills in product development and gain practical insights into real-world challenges.

Course Articulation Matrix: Mapping of Course Outcomes (COs) with Program Outcomes (POs 1-13)

Course Outcomes (COs)/Program Outcomes (POs)	1	2	3	4	5	6	7	8	9	10	11	12	13
Understand the fundamental concepts and stages of the product development process.		✓	✓										
Analyse and mitigate risks associated with product development good laboratory practices (GLP)								✓		✓			
Understand ethical considerations in product development and consumer safety case studies to develop their skills in product development and gain practical insights into real-world challenges		✓						✓		✓			

Program Name	B.Sc. Biotechnology	Semester	6th Semester
Course Title	Product Development		
Course No.	VOC- II	No. of Theory Credits	2+1 (Theory+ Practical)
Contact hours	45 hrs	Duration of ESA/Exam	2hrs
Formative Assessment Marks/ Practical component	20	Summative Assessment Marks	30

Course Outcomes (COs):	
At the end of the course the student should be able to:	
<ol style="list-style-type: none"> 1. Understand the fundamental concepts and stages of the product development process. 2. Analyse and mitigate risks associated with product development. 3. Understand ethical considerations in product development and consumer safety case studies to develop their skills in product development and gain practical insights into real-world challenges. 	
Content	Total 30 Hrs
Unit-I Essentials of Product Development, reporting and documentation	15 Hrs
<p>Company protocols for research, privacy policies, institutional and professional code of ethics and standards of practice, IPR guidelines, Knowledge of basic laboratory procedures, GLP and GMP, relevant EOPs, SOPs, process flows in manufacturing, product life cycle and product properties, competitor products. Stability studies – generate stability data & prepare stability reports for innovation products,</p> <p>Reporting – different standard reference materials used like drugs, products, side effects, adverse reactions, process details, statistical analysis of test data. Documentation – methods and procedures of writing and maintaining lab, research records, research performance reports, schemes and guidelines,</p>	

power point presentations, tables, charts, word documents, development of research objectives and proposal writing for funding and contractual purposes, publications and technical writing, Regulatory compliance of the final documents	
Unit- II Planning and legal considerations in product development	15 Hrs
<p>Research planning – resource, time, timeline & budget considerations, technical feasibility analysis on the NPD ideas by analyzing current development plans, plan day to day activities. Research communications - preparation of progress reports/ research outcomes for steering groups/ bodies, principal investigator, communication with upstream and downstream teams.</p> <p>Research initiatives – use new areas of research, techniques, and methods, extend research/ product portfolio, creative analysis & interpretation of research data. Decision making – collaborative, appropriate, optimum & best possible solution, Trouble- shoot & Resolve problems to avoid delays. Intellectual property rights and patents, Legal and regulatory compliance, Ethical considerations in product development, Identifying and assessing risks in product development.</p>	

Pedagogy: Lectures, Seminars, Industry Visits, Debates, Quiz and Assignments

Course title	Product Development (Practical)	Practical credits	25hrs
Course No.	VOC -II	Contact hours	4hrs/week
Content			
<ol style="list-style-type: none"> 1. Create product Ideation, sketches and product development using digital design 2. Develop product prototypes using low-fidelity materials like cardboard, foam, or 3D printing. 3. Conduct surveys or interviews to gather customer feedback and preferences. 4. Analyze market trends and competition by studying industry reports and conducting online research. 5. Use of tools like Google Trends or social media listening to identify emerging market needs and consumer sentiments. 6. Develop a comprehensive marketing plan for a product launch, including target audience identification, messaging, and promotional activities. 7. Create marketing materials such as brochures, advertisements, and social media content. 8. Develop a comprehensive marketing plan for a product launch, including target audience identification, messaging, and promotional activities. 9. Develop guidelines or policies to address ethical issues in product development. 10. Discuss ethical dilemmas and considerations in product development, such as privacy concerns or environmental impact. 			

Note: Semester end examination is only in the theory component and questions from the practical part could be included, if any.

References:

1. Antonios Fytopoulos, Rohit Ramachandran, Panos M. Pardalos, (2022), Optimization of Pharmaceutical Processes (Springer Optimization and Its Applications, 189) 1st ed.
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 6. Jain, N. (2011). Pharmaceutical product development. New Delhi: CBS Publishers.
 7. Shargel, L. and Kanfer, I. (2010). Generic drug product development. New York: InformaHealthcare USA.
 8. Kanfer, I. and Shargel, L. (2010). Generic drug product development. New York: InformaHealthcare.
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 10. Abraham, J. and Lawton Smith, H. (2003). Regulation of the pharmaceutical industry. Houndmills, Basingstoke, Hampshire: Palgrave Macmillan.
 11. Haider, S. (2002). Validation standard operating procedures. Boca Raton [Fla.]: St. Lucie Press.
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 13. Steven L. Nail and Michael J. Akers (2002), Development and Manufacture of Protein Pharmaceuticals, Pharmaceutical Biotechnology, Volume 14, 1st edition.