Government of Karnataka

Model Curriculum

Program Name	**BSc Biotechnology**		Semester	**Fourth Sem**
Course Title	**Molecular Biology**			
Course No.	**BTC: 104**	**DCS -4T**	No. of Theory Credits	**4**
Contact hours	**56 hrs**		Duration of ESA/Exam	**2.30 Hours**
Formative Assessment Marks			Summative Assessment Marks	

Course Pre-requisite (s):

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

1. Study the advancements in molecular biology with latest trends.
2. Will acquire the knowledge of structure, functional relationship of proteins and nucleic acids.
3. Aware about the basic cellular processes such as transcription, translation, DNA replication and repair mechanisms.

Content	Hrs
Unit–I - Molecular basis of life and Nucleic Acids An introduction RNA and experimental proof of DNA as genetic material and types of DNA.Structure and functions of DNA and RNA, Watson and Crick model of DNA and other forms of DNA (A and Z) functions of DNA and RNA including ribozymes.	**14 Hrs**
Unit -II - DNA Replication and Repair Replication of DNA in prokaryotes and eukaryote– Enzymes and proteins involved in replication, Theta model, linear and rolling circle model. Polymerases and all enzyme components. The replication complex: Pre-primming proteins, primosome, replisome, unique aspects of eukaryotic chromosome replication, Fidelity of replication DNA damage and Repair mechanism: photo reactivation, excision repair, mismatch repair and SOS repair.	**14 Hrs**
Unit -III - Transcription and RNA processing Central dogma, RNA structure and types of RNA, Transcription in prokaryotes RNA polymerase, role of sigma factor, promoter, Initiation, elongation and termination of RNA chains. Transcription in eukaryotes: Eukaryotic RNA polymerases, transcription factors, promoters, enhancers, mechanism of transcription initiation, promoter clearance and elongation RNA splicing and processing: processing of pre-mRNA: 5' cap formation, polyadenylation, splicing, rRNA and tRNA splicing.	14 Hrs
Unit –IV - Regulation of gene expression and translation Genetic code and its characteristics, Wobble hypothesisTranslation- in prokaryotes and eukaryotes- ribosome, enzymes and factors involved in translation. Mechanism of translation-activation of amino acid, aminoacyl tRNA synthesis, Mechanism- initiation, elongation and termination of polypeptide chain. Fidelity of translation, Inhibitors of translation. Protein folding and modifications, Post translational modifications of proteins.	14 Hrs

Course Articulation Matrix: Mapping of Course Outcomes (COs) with Program Outcomes (POs 1-12)

Course Outcomes (COs) / Program Outcomes (POs)	Program Outcomes (POs)											
	1	2	3	4	5	6	7	8	9	10	11	12
Study the advancements in molecular biology with latest trends	✓				✓							✓
Will acquire the knowledge of structure, functional relationship of proteins and nucleic acids					✓	✓						✓
Aware about the basic cellular processes such as transcription, translation, DNA replication and repair mechanisms	✓				✓				✓			✓

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

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

Course Title	**Molecular Biology**		Practical Credits	**2**
Course No.	**BTC: 104**	**DSC-4P**	Contact hours	
Content				

1. Preparation of DNA model
2. Estimation of DNA by DPA method
3. Estimation of RNA by Orcinol method
4. Column chromatography – gel filtration (Demo)
5. Extraction and partial purification of protein from plant source by Ammoniumsulphate precipitation.
6. Extraction and partial purification of protein from animal source by organic solvents.
7. Protein separation by SDS-Polyacrylamide Gel Electrophoresis (PAGE)
8. Charts on- Conjugation, Transformation and Transduction, DNA replication, Types of RNA

Practical assessment

Assessment			
Formative assessment		**Summative Assessment**	**Total Marks**
Assessment Occasion / type	**Weightage in Marks**	**Practical Exam**	
Record	5	25	**50**
Test	10		
Attendance	5		
Performance	5		
Total	**25**	**25**	

References	
1	Glick, B.R and Pasternak J.J (1998) Molecular biotechnology, Principles and application of recombinant DNA, Washington D.C. ASM press
2	Howe. C. (1995) Gene cloning and manipulation, Cambridge University Press, USA
3	Lewin, B., Gene VI New York, Oxford University Press
4	Rigby, P.W.J. (1987) Genetic Engineering Academic Press Inc. Florida, USA
5	Sambrook et al (2000) Molecular cloning Volumes I, II & III, Cold spring Harbor Laboratory Press New York, USA
6	Walker J. M. and Ging old, E.B. (1983) Molecular Biology & Biotechnology (Indian Edition) Royal Society of Chemistry U.K
7	Karp. G (2002) Cell & Molecular Biology, 3rdEdition, John Wiley & Sons; I

Government of Karnataka

Model Curriculum

Program Name	**BSc Biotechnology**		Semester	**Fourth Sem**
Course Title	**Intellectual Property Rights**			
Course Code		**OE-4**	No. of Theory Credits	**3**
Contact hours	**Lecture**		Duration of ESA/Exam	**2.5 Hours**
	Practical			
Formative Assessment Marks			Summative Assessment Marks	

Course Pre-requisite(s): Semester I and II of composite Home Science.

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

1. Knowledge about need and scope of Intellectual property rights
2. Acquire knowledge about filing patents, process, and infringement
3. Knowledge about trademarks, industrial designs, and copyright

Content	**45 Hrs**
Unit–I - Introduction to Intellectual property rights (IPR): Genesis and scope. Types of Intellectual property rights - Patent, Trademarks, Copyright, Design, Trade secret, Geographical indicators, Plant variety protection. National and International agencies – WIPO, World Trade Organization (WTO), Trade-Related Aspects of Intellectual Property Rights (TRIPS), General Agreement on Tariffs and Trade (GATT).	**14 Hrs**
Unit -II - Patenting, process, and infringement Basics of patents - Types of patents; Patentable and Non-Patentable inventions, Process and Product patent. Indian Patent Act 1970; Recent amendments; Patent Cooperation Treaty (PCT) and implications. Process of patenting. Types of patent applications: Provisional and complete specifications; Concept of "prior art", patent databases (USPTO, EPO, India). Financial assistance, schemes, and grants for patenting. Patent infringement- Case studies on patents (Basmati rice, Turmeric, Neem)	**14 Hrs**
Unit -III - Trademarks, Copy right, industrial Designs Trademarks- types, Purpose and function of trademarks, trademark registration, Protection of trademark. Copy right- Fundamentals of copyright law, Originality of material, rights of reproduction, industrial Designs: Protection, Kind of protection provided by industrial design.	**14 Hrs**

Pedagogy

Summative assessment = 40 marks theory paper, End semester Exam duration of exam 2 hours

Formative Assessment Occasion / type	Weightage in Marks (APO)
Assignment	10
Seminar	10
Case studies	10
Test	10
Total	40 marks

References

1. Manish Arora. 2007. Universal's Guide to Patents Law (English) 4th Edition) -Publisher: Universal Law Publishing House
2. Kalyan C. Kankanala. 2012. Fundamentals of Intellectual Property. Asia Law House
3. Ganguli, P. 2001. Intellectual Property Rights: Unleashing the knowledge economy. New Delhi: Tata McGraw-Hill Pub
4. World trade organization - http://www.wto.org
5. World Intellectual Property organization – www.wipo.intOffice of the controller general of Patents, Design & Trademarks - www.ipindia.nic.in

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**
Medical Biotechnology: Scope and Importance. **Microbial diseases in humans:** Mode of infection, symptoms, epidemiology and control measures of diseases caused by Viruses (AIDS, Hepatits-B, Rabies) Bacteria (Typhoid, Cholera, TB, Plague), Fungi (Aspergillosis, Histoplasmosis), Protozoa (Malaria, Amoebiasis). 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.	
Unit II- CLINICAL RESEARCH AND NANOBIOTECHNOLOGY	**15hrs**

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. **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). Applications of nanotechnology: Nano biosensors, Bioremediation, drug and gene delivery, Biochips- analytical devices, disease diagnostics, and cancer therapy Risk potential of nonmaterial.	
Unit III – STEM CELLS AND CANCER BIOLOGY	**15hrs**
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. **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.	
Unit IV- VACCINOLOGY	**15hrs**
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. 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.	

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 11th 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, 3rdedn. 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**
Introduction to the Immune System: History of Immunology, Clonal Selection Theory. Defense against pathogenic organisms – viruses, bacteria, fungi. Types of Immunity: first and second line of defense, innate and acquired/adaptive immunity, specificity, diversity, Self and non-self-recognition. 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. Organs of the Immune system: Thymus, bone marrow, spleen, Lymph Node, peripheral lymphoid organs	
Unit -II Molecules of the Immune System	**15**
Antigens and haptens: Properties (foreignness, molecular size, heterogeneity). Adjuvants. Antigenicity and Immunogenicity. Affinity and Avidity. B and T cell epitopes, superantigens Immunoglobulins: Classification, structure, and function. Monoclonal and polyclonal antibodies. VDJ Gene Segments and DNA rearrangements. Major histocompatibility complexes: Classification, structure, and function. Antigen processing pathways – Cytosolic and Endocytic Cytokines: Classification and function Complement: Pathways	
Unit -III Antigen-Antibody Reactions and Immunotechniques	**15**
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	
Unit - IV	**15**
Vaccines: Conventional, peptide vaccines, subunit, DNA vaccines. Toxoids, antisera, edible vaccines, plantibodies, ISCOMs, recombinant antibodies, and Cancer vaccines. Transplantation immunology: Phases in graft rejection and immuno-suppressors. Hypersensitivity: Reactions – Types I, II, and III. Delayed Type Hypersensitive Response. Autoimmune Disorders: Systemic and Organ-specific Autoimmune disorders with examples Immunodeficiencies: Primary and secondary immunodeficiencies; acquired immunodeficiency syndrome Cancer and the immune system – immune surveillance, immunological escape, cancer antigens, cancer immunotherapy	

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

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**	**25**	

References

1. Textbook of Immunology, Paul Ajoy, Books and Allied (P) Ltd., 2016
2. Kuby Immunology. Kindt T.J. et at., 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

9. Instant Notes in Immunology. Lydyard PM et al. Viva Books Pvt. Ltd., 2011
10. Abbas AK, Lichtman AH, and Pillai S. (2019). Basic Immunology- Functions and Disorders of the Immune System. Elsevier,
11. Abdul, K., Abbas, Andrew K. L., Jordan, S. P. (1998). Cellular and Molecular Immunology. W.B Saunders Publisher. Philadelphia.
12. Benjamine, E., Cocoi., Sunshine. (2000). Immunology 4th edition- Wiley-Liss. New York.
13. Borrebacc, C.A.K. (1995). Antibody Engineering, 2nd edition. Oxford University Press, Oxford.
14. Dimmock, N.J., Primrose, S.B. (1994). Introduction to Modern Virology, Blackwell Science Ltd Oxford.
15. Hyde, R.M. (1992). Immunology, 2nd edition, Williams and Wilkins, Baltimore.
16. Kuby, J. (2003). Immunology 5th Edition. WH. Freeman and Company, NY.
17. Klaus D. Elgert (1996). Immunology. ELBS, Blackwell Scientific Publishers, London.
18. Roitt, I.M. (2017). Essential Immunology, Thirteenth edition, ELBS, Wiley Blackwell Scientific Publishers, London.
19. Goldsby, R.A, Kindt TJ and Osborne A (2000). Kuby Immunology, 4th edition, W.H. Freeman and Company, New York
20. Tizard I.R. (1995). Immunology, 4thedition, W.B. Saunders Publisher. Philadelphia.
21. Paul W.E (1989). Fundamentals in Immunology, Raven Press. NY.

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

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

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.
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10. Paulins, M. D. Bioprocess Engineering Principles. John Wiley Publishers.2003.
11. Prentice Hall, Engelwood Cliffs, 2002.
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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, *in vitro* 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, *in-situ* 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.
14. Ram P Rastogi, Compendium of Indian Medicinal Plants Vol. I-V, CSIR, Lucknow & NISCOM, New Delhi, 1998.
15. Cupp M.J., Toxicology and Clinical Pharmacology of Herbal Products, Humana Press, New Jersy, 2000.
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-1	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:

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**
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 ofprogress reports/ research outcomes for steering groups/ bodies, principal investigator, communication with upstream and downstream teams 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 & bestpossible solution, Troubleshoot & Resolve problems to avoid delays. 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	

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			
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:

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

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, relevantEOPs, SOPs, process flows in manufacturing, product life cycle and product properties, competitor products. Stability studies – generate stability data & prepare stability reports for innovation products,

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,

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**
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 upstreamand downstream teams. 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.	

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			
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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3. Hameel, F., Hershenson, S., Khan, M. and Martin-Moe, S. (n.d.). Quality by design for biopharmaceutical drug product development.
4. Krattiger, A., Mahoney, R., Nelsen, L., Thomson, J., Bennett, A., Satyanarayana, K., Graff,

G., Fernandez, C. and Kowalski, S. (2007). Intellectual property management in health and agriculture innovation. Oxford, U.K.: MIHR.
5. Haider, S. and Asif, E. (2011). Quality control training manual. Boca Raton: CRC Press.
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.
9. Reklaitis, G., García-Munoz, S. and Seymour, C. (n.d.). Comprehensive quality by designfor pharmaceutical product development and manufacture.
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. LuciePress. Guirdham, M. (1990). Interpersonal skills at work. New York: Prentice-Hall.
12. Improving New Product Development: Bausch. (2004). [Place of publication not identified]:American Productivity & Quality Center (APQC).
13. Steven L. Nail and Michael J. Akers (2002), Development and Manufacture of Protein Pharmaceuticals, Pharmaceutical Biotechnology, Volume 14, 1st edition.