



# Syllabus

## Third Semester Courses in

### MSc

# BIOTECHNOLOGY

## (2024-2025)

### Contents:

- **Syllabus for Core Courses:**
  - PSBTY6501CR1 Bioprocess Technology
  - PSBTY6502CR1 Pharmaceutical Biotechnology
  - PSBTY6503CR1 Biotechnology Enterprise
  - PSBTY6501RP1 Research Project
- Evaluation and Assessment guidelines

**APPROVED SYLLABUS**



PRINCIPAL  
ST. XAVIER'S COLLEGE  
AUTONOMOUS  
MUMBAI - 400 001.

<b>MSc II in BIOTECHNOLOGY</b>		
<b>Course Title: BIOPROCESS TECHNOLOGY</b>		<b>Course Code: PSBTY6501CR1</b>
Credits 4: Theory = 60 hrs		
<b>No.</b>	<b>Course Objectives</b>	
1.	The course aims at educating students about the strategies employed in process industries and its implementation into biological systems to produce valuable biotech-based metabolites.	
2.	The engineering concepts including cell growth kinetics, process design, and transport operation, downstream processing will be covered during the course.	
3.	Students will have a comprehensive understanding of bioprocess operations along with practical skills in applying these concepts to optimize microbial processes at an industrial scale.	
<b>CO</b>	<b>Course Outcomes</b> <i>On completing the course, the learner will be able to</i>	<b>Bloom's Taxonomy Level (BT level)</b>
1.	Understand the microbial processes and parameters controlling them. Explore stoichiometry of microbial growth and product formation.	Remembering
2.	Comprehend the various industrial substrates, growth media, energy, and material balances, gas and mass transfer, and downstream processes. Understand the advantages and challenges associated with bioprocess.	Understanding
3.	Apply the acquired knowledge in designing and optimizing microbial processes across different operational modes.	Applying
4.	Analyze real-world case studies of industrial microbial processes. Gain insights into optimizing process parameters for enhanced microbial performance.	Analyzing
5.	Develop problem-solving abilities in the context of microbial growth, process optimization, substrate utilization, product formation and effluent treatment.	Evaluating, Creating



<b>UNIT I</b>	<b>PRINCIPLES OF BIOPROCESS TECHNOLOGY</b>	<b>(15)</b>
	1. Industrial substrates and growth medium	
	2. Energy and Material Balances - Introduction to material-balance calculations, stoichiometry of microbial growth and product formation, energy – balance calculations with and without reactions	
	3. Kinetics of microbial growth, substrate utilization, and product formation: Batch, Fed-Batch and continuous processes	
	4. Scale up concepts and its challenges	
	5. Solid state fermentation	
	6. Processes using recombinant organisms: hosts, vectors, genetic instability.	
<b>UNIT II</b>	<b>PROCESS DYNAMICS AND OPERATIONS</b>	<b>(15)</b>
	1. Mass transfer: Review of basic concepts – Diffusivity, theory of diffusion, role of diffusion in bioprocessing, mass transfer coefficients, Theories of mass transfer, Convective mass transfer – Liquid-solid mass transfer, liquid-liquid mass transfer, gas liquid mass transfer.	
	2. Oxygen transport to microbial cultures: Gas exchange; O <sub>2</sub> transfer, critical oxygen concentration, determining the oxygen uptake rate.	
	3. Heat transfer: Sterilization –batch and continuous heat sterilization, filter sterilization of liquid media and air. Design of sterilization equipment. thermal death curve.	
<b>UNIT III</b>	<b>DOWNSTREAM PROCESSING</b>	<b>(15)</b>
	1. Flocculation and floatation	
	2. Filtration	
	3. Centrifugation	
	4. Cell disruption	
	5. Liquid extraction	
	6. Precipitation and Adsorption	
	7. Dialysis and Reverse osmosis	
	8. Chromatography	
	9. Crystallization and drying	



UNIT IV	INDUSTRIAL APPLICATIONS	(15)
1.	Microbial technology in food production: Role of microbial fermentation in food and beverages; food ingredients and additives prepared ; Bioconversion from food wastes to useful products; Food preservation via microbes	
2.	Role of microbes in effluent treatment	
3.	Biopolymers/micro-polymers	
4.	Antibiotics	
5.	Vitamins	
6.	Amino acids and alcohols	
7.	Immobilized cell systems	
8.	Types and nature of waste generated from bioprocesses.	
9.	Case studies	

**Reference Books:**

- Alvarado-Morales, M., & Angelidaki, I. (2021). Valorization of municipal organic waste into purified lactic acid Bioresource Technology, 342, 125933. <https://doi.org/10.1016/j.biortech.2021.125933>
- Baranwal, J., Barse, B., Fais, A., Delogu, G. L., & Kumar, A. (2022). Biopolymer: A Sustainable Material for Food and Medical Applications. Polymers, 14(5),983. <https://doi.org/10.3390/polym14050983>
- Danial, A. W., Hamdy, S. M., Alrumman, S. A., Gad El-Rab, S. M. F., Shoreit, A. A. M., & Hesham, A. E.-L. (2021). Bioplastic Production by Bacillus wiedmannii AS-02 OK576278 Using Different Agricultural Wastes. Microorganisms, 9(11), 2395. <https://doi.org/10.3390/microorganisms9112395>
- Glazer A.N. & Nikaido H. (1995) *Microbial Biotechnology: Fundamentals of Applied Microbiology*. W.H. Freeman & Company, New York.
- López-Gómez, J., Pérez-Rivero, C., & Venus, J. (2020). Valorisation of solid biowastes: The lactic acid alternative. Process Biochemistry, 99,222–235. <https://doi.org/10.1016/j.procbio.2020.08.029>
- Matkawala, F., Nighojkar, S., Kumar, A., & Nighojkar, A. (2021). Microbial alkaline serine proteases: Production, properties and applications. World Journal of Microbiology and Biotechnology, 37, 1-12.
- Michael L. Shuler, Fikret Kargı (2008) *Bioprocess Engineering: basic concepts*. Prentice Hall Publishers. New York.
- Nath, P. C., Ojha, A., Debnath, S., Sharma, M., Nayak, P. K., Sridhar, K., & Inbaraj, B. S. (2023). Valorization of Food Waste as Animal Feed: A Step towards Sustainable Food Waste



Management and Circular Bioeconomy. *Animal*, MDPI, 13(8), 1366.  
<https://doi.org/10.3390/ani13081366>

9. Pauline M. Doran, *Bioprocess Engineering Principles*. Academic Press, 1995.
10. Singhal, G., Bhagyawant, S. S., & Srivastava, N. (2020). Microbial enzymes in food industry: Types and applications. In *Microbial Fermentation and Enzyme Technology* (pp. 61-71). CRC Press.
11. Stanbury P.F., Whitaker A, Hall S.J. (2007) *Principles of Fermentation Technology*, Butterworth-Heinemann
12. Wulf Crueger and Anneliese Crueger (1990) *Biotechnology: A Textbook of Industrial Microbiology*. Panima Publishers. New Delhi

**Evaluation (Core Theory): Total marks per course – 100.**

- Formative Assessment ‘for’ Learning (continuous internal assessment - CIA to improve learning).  
CIA- 40 marks  
CIA 1: Written test -20 marks  
CIA 2: Assignment -20 marks
- Summative Assessment ‘of’ Learning (focus on outcomes, quantitative data for outcomes of instruction).  
End Semester Examination – 60 marks.  
One question from each unit for 15 marks, with internal choice. Total marks per question with choice -20 to 22.

**Distribution of Bloom’s Taxonomy Levels for the Course Assessment**

Units	Remembering	Understanding	Analyzing And Application	Evaluation and Creation
*Percentage	10-20%	30-35%	30-40%	20-25%

<b>MSc II BIOTECHNOLOGY</b>		
<b>Course Title: PHARMACEUTICAL BIOTECHNOLOGY</b>		
<b>Course Code: PSBTY6502CR1</b>		
Credits 4 (Theory) 60 hours		
<b>No.</b>	<b>Course Objectives</b>	
1.	The course will provide an insight into the research and development carried out in discovery of biotechnology based therapeutic peptides and proteins.	
2.	This course will give students a brief overview of formulation of biological compounds citing various examples and processes involved.	
3.	The core of this course will encompass the journey of the biologic from bench to bedside.	
<b>CO</b>	<b>Course Outcomes</b> <i>On completing the course, the learner will be able to</i>	<b>Bloom's Taxonomy Level (BT level)</b>
1	Demonstrate fundamental knowledge in the process of biologics drug discovery	Remembering, Understanding
2	Apply pharmacokinetic-pharmacodynamic (PKPD) principles to analyze the behavior of protein-based therapeutics in vivo	Applying
3	Understand and apply CADD methods in various stages of the drug discovery pipeline,	Understanding, Applying
4	Analyze case studies highlighting successful biopharmaceutical drug discovery and development efforts	Analyzing
5	Demonstrate knowledge and will be equipped with skills, and techniques necessary to formulate, analyze, and evaluate biotech-based products in preclinical settings, ensuring their safety, efficacy, and compliance with regulatory requirements.	Analyzing, Evaluating,
6	Evaluate safety and ethical considerations in drug development and contribute effectively to the discovery and development of novel therapeutic agents.	Evaluating and creating



<b>UNIT I</b>	<b>Pharmacology aspects of Peptide and Protein therapeutics</b>	<b>(15)</b>
	1. Introduction to Biopharmaceuticals, Differences between small molecule drugs, generics, Biologics and Biosimilars	
	2. Basic characteristics of of therapeutic peptides and proteins : Temperature and stress sensitive, sensitive to pressure and solvent, aggregation behavior, degradation pattern, difference between degradation, aggregation and precipitation ,stability and characterisation	
	3. Principles of pharmacokinetics and pharmacodynamics :	
	4. Terminologies, Drug-receptor interactions, Drug transporters, Drug Enzyme interactions, Drug Metabolism	
	5. PKPD of Protein based therapeutics.	
	6. Immunogenicity of therapeutic proteins	
<b>UNIT II</b>	<b>Drug Discovery approaches (Practicals included)</b>	<b>5L</b>  <b>10PR</b> <b>sessions</b>
	1. Introduction to drug discovery and development [ Introduction, concept, history, drug development process outline, concept of ligand and target]	
	2. Drug discovery approaches - Traditional screening and CADD.	
	3. Ligands: [agonists, inhibitors, and allosteric modulators]	
	4. Target: Classes of molecular target, Target identification	
	5. Drug and drug databases ; Drug Properties	
	6. Computer-Aided Drug Design in the Drug Discovery Pipeline [Structure based CADD, Ligand Based CADD]	
	7. Case Studies	
<b>UNIT III</b>	<b>Formulation And Preclinical Aspects of Biotech Based Products</b>	<b>(15)</b>
	1. Microbiological considerations- Sterility, Decontamination Pyrogen removal	
	2. Excipients and additives Role of excipients and additives on stabilizing biologicals; Pharmacopoeia approved excipients, additives and stabilizers, anti-aggregation agents, buffer components etc	
	3. Formulation and delivery systems: Characteristics of liquid, powder formulation, particulate formulation for biologicals, liposomal	



	<p>formulation and solid lipid nanoparticle formulation. Different nano carrier-based formulation; Examples of biological formulation: Insulin formulation, formulation of monoclonal antibodies, vaccines in pharmacotherapy</p>	
4.	<p><b>Product Analysis- Protein-based contaminants</b></p> <ul style="list-style-type: none"> <li>• Removal of altered forms of the protein of interest from the product stream</li> <li>• Detection of protein-based product impurities</li> <li>• Immunological approaches to detection of contaminants</li> <li>• Endotoxin and other pyrogenic contaminants</li> <li>• Microbial and viral contaminants</li> <li>• Miscellaneous contaminants</li> </ul>	
5.	<p><b>Preclinical <i>Invitro</i> -<i>Invivo</i> testing methods.</b></p> <p><i>Invitro</i> Cytotoxicity, Genotoxicity</p> <p>Regulatory Toxicology (including ICH guidelines):</p> <p>Acute vs Chronic studies (selection of species, duration and evaluation)</p> <p>Safety Pharmacology- Mutagenicity and Carcinogenicity studies, Reproductive and Developmental Toxicology studies, Mechanistic Toxicology (including biomarkers)</p> <p>New trends in preclinical evaluation- NAMs- 3D cultures, organ on a chip models.</p>	
<b>UNIT IV</b>	<b>Regulations and ethical concerns in Drug Development (Biologics)</b>	<b>(15)</b>
1.	<p><b>Biosafety- Primary containment for biohazards; biosafety levels; GRAS organisms, biosafety levels of specific microorganisms; recommended biosafety levels for infectious agents ,definition of GMOs, LMOs</b></p>	
2.	<p><b>Framework for Regulations in Recombinant DNA technology usage :</b> Convention on Biological Diversity, Cartagena Protocol on Biosafety, WTO Agreements, Codex Alimentarius, Role of IBSC, RCGM, GEAC, and others, National Biotechnology Regulatory Bill 2013, The DNA Technology (Use and Application) Regulation Bill – 2019, Recombinant DNA Research and Biocontainment guidelines-2017</p>	
3.	<p><b>Risk assessment- risk characterization and development of analysis plan (management and communication including GMP, GLP, and HACCP)</b></p>	
4.	<p><b>Clinical Trials and regulatory framework:</b></p>	

	<p>Good clinical practice guidelines, Clinical Trial Phases: Objectives of Phase I, II, III and IV clinical studies , Pharmacovigilance- Adverse reactions monitoring and reporting.</p> <p>Regulatory requirements: FDA, EMA, CDSCO</p> <p>Ethical aspects - patient confidentiality, informed consent, Human and animal experimentation, animal rights/welfare, sharing benefits and protecting future generations.</p>	
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**Reference Books:**

1. *Biologicals*. (n.d.). CDSCO. <https://cdsco.gov.in/opencms/opencms/en/biologicals/>
2. Brody, T. (2016). *Clinical trials: Study design, endpoints and biomarkers, drug safety, and FDA and ICH guidelines*. Academic Press.
3. *CFR - Code of federal regulations title 21*. (2023, December 22). <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=600>
4. Crommelin, D. J., & Sindelar, R. D. (2002). *Pharmaceutical biotechnology: Fundamentals and applications* (2nd ed.). CRC Press.
5. *Good manufacturing practices*. (n.d.). World Health Organization (WHO). <https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp>
6. *Guidance, compliance & regulatory information (Biologics)*. (2022, December 14). U.S. Food and Drug Administration. <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>
7. *ICH official web site : ICH*. (n.d.). ICH Official web site : ICH. <https://www.ich.org/page/ich-guidelines>
8. Jacobsen, T., & Wertheimer, A. (2016). *Modern pharmaceutical industry*. Kendall/Hunt Publishing Company.
9. Kayser, O., & Müller, R. H. (2006). *Pharmaceutical biotechnology: Drug discovery and clinical applications*. John Wiley & Sons.
10. Laurence L. Brunton, Björn C. Knollmann. (2001). *Goodman & Gilman's: The Pharmacological Basis of Therapeutics*, (14th ed.). Tata McGraw Hill.
11. Nally, J. D. (2016). *Good manufacturing practices for pharmaceuticals*. CRC Press.
12. Schüklenk, U., & Singer, P. (2021). *Bioethics: An anthology*. John Wiley & Sons.
13. Stromgaard, K., Krogsgaard-Larsen, P., & Madsen, U. (2016). *Textbook of drug design and discovery* (5th ed.). CRC Press.
14. Walsh, G. (2013). *Biopharmaceuticals: Biochemistry and biotechnology*. John Wiley & Sons.
15. Walsh, G. (2013). *Pharmaceutical biotechnology: Concepts and applications*. John Wiley & Sons.



**Evaluation (Theory, PSBTY6502CR1): Total marks per course – 100**

- Formative Assessment ‘for’ Learning  
(continuous internal assessment - CIA to improve learning).

**CIA - 40 marks**

CIA 1: Written test - 20 marks.

CIA 2: Test / Assignment / Presentations / Infographics / Quiz / as prescribed - 20 marks.

- Summative Assessment ‘of’ Learning  
(focus on outcomes, quantitative data for outcomes of instruction)

**End Semester Examination - 60 marks**

One question from each unit for 15 marks, with internal choice. Total marks per question with choice -20 to 22.

**Distribution of Bloom’s Taxonomy levels for the course assessment**

Learning Levels	Remembering	Understanding	Analyzing and Application	Evaluation	Creation
*Percentage	10-15%	25-35%	20-25%	15-20%	10-15%



<b>MSc II BIOTECHNOLOGY</b>		
<b>Course Title: BIOTECHNOLOGY ENTERPRISE</b>		
<b>Course Code: PSBTY6503CR1</b>		
Credits 4: Theory= 60 hrs		
No.	Course Objectives	
1.	The course is formulated to foster a deeper understanding of the complex interactions between biotechnology, ecosystems, and human society in shaping environmental sustainability.	
2.	The course will offer an overview of the fundamentals of patent law, exploring its regional and global regulations, specifically focusing on their application in safeguarding biotechnological inventions.	
3.	The course will elaborate on the strategic considerations involved in biotechnology entrepreneurship	
CO	Course Outcomes <i>On completing the course, the learner will be able to</i>	Bloom's Taxonomy Level (BT level)
1.	Analyze the role of biotechnological tools such as genetic engineering, bioremediation, and biofuels in mitigating environmental degradation.	Analysing ,Applying
2.	Apply principles of intellectual property law to facilitate the commercialization of biotechnology research and product generation.	Applying
3.	Employ the fundamental aspects of entrepreneurship to write and review a business plan	Creating

UNIT I	Biotechnology and Environmentally Sustainable Development	(15)
	1. Definition and concepts of sustainable development, Integration of: a. Economic, Social and Environmental sustainability	
	2. Environmental sustainability and role of biotechnology	
	3. Carbon sequestration, Carbon footprint and credits	



	4.	Biomass management and value added products	
	5.	Sustainability in agriculture: Bio-pesticides, Bio-fertilizers	
	6.	Energy and Environment: Bioenergy	
	7.	IOT for water and air quality monitoring	
	8.	Case studies	
<b>UNIT II</b>		<b>Basic Concepts of IPR</b>	<b>(15)</b>
	1.	Basics of IPR, Types of IPR, Biotechnology and the law: objective, evolution, Commercial potential of biotech inventions, rationale for IPR protection, Permissible and non-permissible Biotechnology patenting in India, Indian Patent Act 1970	
	2.	Patenting biotech inventions: objectives, concepts of novelty and concepts of inventive step, microorganisms, and moral issues in patenting biotech inventions	
	3.	Patenting issues related to Biosimilars	
	4.	Protection of geographical indications: objectives, justification, international position, multilateral treaties, national level	
	5.	Protection of traditional knowledge: objective, the concept of traditional knowledge, sui generis regime, bio-prospecting and bio-piracy, protectability, traditional knowledge on the international arena, traditional knowledge at WTO, traditional knowledge at the national level, traditional knowledge digital library	
	6.	Plant varieties protection: objectives, justification, criteria for protection, international position, plant varieties protection in India, plant varieties protection under TRIPS	
	7.	Case studies	
<b>UNIT III</b>		<b>Patent Search &amp; Analysis</b>	<b>(15)</b>
	1.	Patent Treaty: WIPO Treaties; Budapest Treaty; Patent Cooperation Treaty (PCT) and implications; procedure for filing a PCT application;	

	<p>role of a Country Patent Office; filing of a patent application; precautions before patenting-disclosure/non-disclosure-patent application- forms and guidelines including those of National Bio-diversity Authority (NBA) and other regulatory bodies, fee structure, time frames; types of patent applications: provisional and complete specifications; PCT and conventional patent applications; international patenting-requirement, procedures and costs; financial assistance for patenting.</p>	
	<p>2. Introduction to existing schemes; publication of patents-gazette of India, status in Europe and US; patent infringement- meaning, scope, litigation, case studies and examples; commercialization of patented innovations; licensing – outright sale, licensing, royalty;</p>	
	<p>3. Patenting by research students and scientists-university/organizational rules in India and abroad, collaborative research - backward and forward IP; benefit/credit sharing among parties/community, commercial (financial) and non-commercial incentives</p>	
	<p>4. Patent reviews and Case studies</p>	
	<p>5. Patent databases - country-wise patent searches (USPTO, EPO, India)</p>	
<b>UNIT IV</b>	<b>Principles of Entrepreneurship and Business plan</b>	<b>(15)</b>
<b>A</b>	<p>Entrepreneurship</p> <p>1 Definition, characteristics, qualities and functions of entrepreneurs; Entrepreneurial, entrepreneurial motivation; Entrepreneurship Theories</p> <p>2 Entrepreneurship types: Social entrepreneurship and Technology entrepreneurship, Family business; Startup landscape and innovation hubs; Entrepreneurship: Role in economic development. Entrepreneurial climate in India; Financial support - funding and policy support, Start-up India Programme [BIRAC/BIG, Business Incubation and other schemes] Case studies on biotech start ups</p>	
<b>B</b>	Business Plan	

	3	Business concept: Idea selection, brainstorming, project planning, conceptualization and feasibility report, Idea generation and Product planning, process design, IP generation, Project cost estimate, project profits	
	4	Sources of Finance: Venture capital, angel investment, crowdfunding. Mechanics of setting up new enterprises –forms of business organization.	

**Reference Books:**

1. David Pressman (2016) *Patent It Yourself* 18<sup>th</sup> edition, Nolo Publishers
2. Jördening, H. J., & Winter, J. (Eds.). (2005). *Environmental biotechnology: concepts and applications*.
3. Maarten Bode, (2008) *Taking traditional knowledge to the market*, Orient Longman Publishers
4. Matei, F., & Zirra, D. (Eds.). (2019). *Introduction to Biotech Entrepreneurship: From Idea to Business: A European Perspective*. Springer International Publishing.
5. Prabudha Ganguly, (2001) *Intellectual Property rights- unleashing the knowledge economy*, Tata McGraw Hill Publishing Company Ltd.
6. Ratledge, C., & Kristiansen, B. (Eds.). (2006). *Basic biotechnology*. Cambridge University Press.
7. Rosillo-Calle, F., & Woods, J. (2012). *The biomass assessment handbook (Vol. 4)*. Taylor & Francis.
8. Sharma, N., Sodhi, S., & Abhinashi, B. (2022). *Basic concepts in environmental biotechnology*.
9. Shimasaki, C. (Ed.). (2020). *Biotechnology Entrepreneurship: Leading, Managing and Commercializing Innovative Technologies*. Academic Press.
10. Sudeep Chaudhuri (2005), *the WTO and India's Pharmaceutical industry*, Oxford University Press.
11. Vandana Shiva (2002), *Protect or Plunder? Understanding Intellectual Property Rights*, Zed Books.
12. Wang, L. K., Ivanov, V., Tay, J. H., & Hung, Y. T. (Eds.). (2010). *Environmental biotechnology (Vol. 10)*. Springer Science & Business Media.



**Research articles:**

1. Bobulski, J., Szymoniak, S., & Pasternak, K. (2024). An IoT System for Air Pollution Monitoring with Safe Data Transmission. *Sensors*, 24(2), 445.
2. Fenibo, E. O., Ijoma, G. N., & Matambo, T. (2021). Biopesticides in sustainable agriculture: A critical sustainable development driver governed by green chemistry principles. *Frontiers in Sustainable Food Systems*, 5, 619058.
3. Ganesan, R., Manigandan, S., Samuel, M. S., Shanmuganathan, R., Brindhadevi, K., Chi, N. T. L., & Pugazhendhi, A. (2020). A review on prospective production of biofuel from microalgae. *Biotechnology Reports*, 27, e00509.
4. Hughes, J. (2013). *Bowman v. Monsanto Company*. *Public Land & Resources Law Review*, (4), 1-2. (<https://core.ac.uk/download/pdf/232675921.pdf>)
5. Knox, R., & Curfman, G. (2022). The Humira patent thicket, the Noerr-Pennington doctrine and antitrust's patent problem. *Nature biotechnology*, 40(12), 1761–1763. (<https://doi.org/10.1038/s41587-022-01583>)
6. Kumar J, Ramlal A, Mallick D, Mishra V. An Overview of Some Biopesticides and Their Importance in Plant Protection for Commercial Acceptance. *Plants (Basel)*. 2021 Jun 10;10(6):1185.
7. Ledford, H. (2021). Inside the lawsuit that ended US gene patenting *Nature*,598(7882),561–562.( <https://doi.org/10.1038/d41586-021-02905-9>)
8. McLaughlin, H., Littlefield, A. A., Menefee, M., Kinzer, A., Hull, T., Sovacool, B. K., ... & Griffiths, S. (2023). Carbon capture utilization and storage in review: Sociotechnical implications for a carbon reliant world. *Renewable and Sustainable Energy Reviews*, 177, 113215.
9. Miller M, Kisiel A, Cembrowska-Lech D, Durluk I, Miller T. IoT in Water Quality Monitoring-Are We Really Here? *Sensors (Basel)*. 2023 Jan 14;23(2):960.
10. Nayak, N., Mehrotra, R., & Mehrotra, S. (2022). Carbon biosequestration strategies: A review. *Carbon Capture Science & Technology*, 4, 100065.
11. Patent docs:Barry V. Medtronic, inc. (Fed. Cir. 2019). (n.d.).(<https://www.patentdocs.org/.m/2019/01/barry-v-medtronic-inc-fed-cir-2019.html>)



12. Patents for medical and surgical methods and diagnostics: Gestalt law. GESTALT. (n.d).  
(<https://www.gestalt.law/insights/patents-for-medical-and-surgical-methods-and-diagnostics>)
13. Simmons, W. J. (2013). Bowman v. Monsanto and the protection of patented replicative biologic technologies. Nature Biotechnology, 31(7), 602-606.

**Evaluation (Theory, PSBTY6503CR1): Total marks per course – 100**

- Formative Assessment ‘for’ Learning  
**CIA - 40 marks**  
CIA 1: Written test - 20 marks.  
CIA 2: Test / Assignment / Presentations / Quiz / as prescribed - 20 marks.
- Summative Assessment ‘of’ Learning  
**End Semester Examination - 60 marks**  
One question from each unit for 15 marks, with internal choice.  
Total marks per question with choice 20 - 22 marks.

**Distribution of Bloom’s Taxonomy Levels for the Course Assessment**

Units	Remembering	Understanding	Analyzing And Application	Evaluation and Creation
*Percentage	NA	45-50%	30-40%	20-25%



<b>MSc II in BIOTECHNOLOGY</b>		
<b>Course Title:</b>		<b>RESEARCH PROJECT</b>
<b>Credits: 6</b>		<b>Practical Course</b>
	<b>Course Objectives</b>	
	<ul style="list-style-type: none"> <li>The focus of the course is on research, research planning, and research reporting.</li> <li>Learners will be encouraged to undertake independent research that makes an original contribution to knowledge.</li> <li>Plan and manage a complex project within strict time constraints.</li> <li>Comply with relevant ethical, safety, and documentation processes as appropriate for the project.</li> </ul>	
<b>CO</b>	<b>Course Outcomes</b> <i>On completing the course, the learner will be able to</i>	<b>Bloom's Taxonomy Level (BT level)</b>
1	Demonstrate an ability to plan a research project, and author a research proposal	Applying
2	Demonstrate adequate knowledge in the subject of their research project, through an integrated literature review, application of research methods appropriate to generate reliable data for their research questions	Applying, and analyzing
3	Show proficiency in managing time effectively and utilizing expertise both independently and within a team setting.	Applying
4	Exhibit the capacity to gather research findings, analyze and integrate them with existing literature, and present them in a globally recognized format that is clear, concise, and impartial.	Analyzing, Evaluating, and creating
5	Display the capability to reflect on the strengths and weaknesses of their research and methodology, offering constructive feedback on how to enhance future endeavors.	Evaluating and analyzing



Content		12 -16 hours/week
	<p>Each student will work as a part of one group project covering the aspects of core concepts of Microbiology, Molecular biology, Environment Biotechnology, Bioinformatics and Animal Cell technology, supervised by the faculty member for a period of three months in the department.</p> <p>The research work will be divided into evaluative phases.</p> <p>Phase 1- Ideation, Literature Review and Proposal writing</p> <p>Phase 2- Research work, Data generation and analysis</p> <p>Phase 3- Report writing</p>	

**Evaluation (Practical- Research Project, PSBTY6501RP1):****Total marks– 300**

Formative Assessment ‘for’ Learning

- CIA-120 marks
- Phase 1 submission and presentation – 40
- Phase 2 -Continuous assessment of work done –80

Summative Assessment ‘of’ Learning

- End Semester Examination – 180 marks.
- Report Submission and Presentation- 140 marks.
- *Viva Voce*- 40 marks.

**Distribution of Bloom’s Taxonomy Levels for the Course Assessment**

Units	Remembering	Understanding	Analyzing And Application	Evaluation and Creation
*Percentage	NA	35-40%	30-40%	20-25%





# Syllabus

## Third Semester Courses in

### MSc

### Biotechnology

### (2024-2025)

Contents:

- **Syllabus for Elective Courses:**
  - PSBTY6501EL1 Clinical Drug Development
  - PSBTY6502EL1 Applications of Informatics in Biotechnology
- Evaluation and Assessment guidelines

**APPROVED SYLLABUS**



  
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MUMBAI - 400 001.

<b>MSc II Biotechnology</b>		
<b>Course Title: CLINICAL DRUG DEVELOPMENT Course Code: PSBTY6501ELI</b>		
<b>Credits 4: ( Theory and Practical) 60 hr.</b>		
<b>COLLABORATOR: Tata Consultancy Services- under the TCS-driven Academic Interface programme (under MOU)</b>		
<b>No.</b>	<b>Course Objectives</b> The industry oriented and curated course aims to provide the learners with the following	
	<ul style="list-style-type: none"> <li>Gain a deep understanding of the domains in drug development process, from early-stage clinical research to Clinical data management.</li> <li>Gain insights into the process of drug safety surveillance and its documentation process.</li> <li>Regulatory Proficiency by attaining knowledge about regulatory affairs and in navigating the complex regulatory landscape governing pharmaceuticals and biotechnology.</li> <li>Learn the importance of ethical considerations, and data integrity in clinical research.</li> <li>Acquire practical skills and knowledge directly applicable to careers in pharmaceutical companies, clinical research organizations (CROs) and regulatory bodies</li> </ul>	
<b>CO</b>	<b>Course Outcomes</b> <i>On completing the course, the learner will be able to</i>	<b>Bloom's Taxonomy Level (BT level)</b>
1	Comprehend about the domains involved in Clinical Research. Understand and demonstrate proficiency in the fundamental principles and techniques of clinical data management.	Remembering, Understanding
2	Comprehend important aspects of pharmacovigilance, and gain a deep understanding of the regulatory framework governing pharmaceuticals and healthcare products	Understanding Applying, Evaluating
3	Implement data collection tools and ensure data accuracy and integrity throughout the trial	Applying, Analyzing, Evaluating
4	Implement the technical writing skills in creating compliant documents for diverse scientific needs in the pharmaceutical industry.	Applying, Analyzing, Creating



<b>UNIT I</b>	<b>Introduction to Clinical Drug Development</b>	<b>(15)</b>
	1. Overview of Drug Discovery & Development , Overview of Clinical Research .	
	2. Overview of Clinical Trial Process	
	3. Overview of GxP guidelines; Overview of Ethical considerations and ICH GCP Guidelines .	
<b>UNIT II</b>	<b>Clinical Data Management</b>	<b>(15)</b>
	1. Overview of Clinical Data Management	
	2. Clinical Database programming and Management Plan	
	3. Medical Coding Dictionaries and other tools for CDM	
<b>UNIT III</b>	<b>Pharmacovigilance and Regulatory Affairs</b>	<b>(18)</b>
	1. Overview to Pharmacovigilance	
	2. Overview to Regulatory Authorities and Regulations	
	3. Adverse events and reporting methods.	
	4. ICH guidelines	
	5. Global Regulatory requirements	
<b>UNIT IV</b>	<b>Communication Formats</b>	<b>(12)</b>
	1. Essentials in communication of complex data	
	2. Scientific Communication formats	
	3. Formats of Clinical trial documents	
	4. Ethical practices in medical writing	

**List of Recommended resources :**

- Centre, U. M. (n.d.). *WHODrug global*. Uppsala Monitoring Centre | UMC. <https://who-umc.org/whodrug/whodrug-global/>
- *ClinicalTrials.gov*. (n.d.). ClinicalTrials.gov. <https://clinicaltrials.gov/study-basics-glossary>
- *Comisión federal para la Protección contra Riesgos Sanitarios | Gobierno | gob.mx*. (n.d.). El portal único del gobierno. | gob.mx. <https://www.gob.mx/cofepris/en>



- *Data management in clinical research: An overview.* (2012, March). PubMed Central (PMC). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3326906/>
- GCDMP©. (n.d.). Society for Clinical Data Management (SCDM). <https://scdm.org/gcdmp/>
- Good-pharmacovigilance-practices-module-v-risk-management-systems-rev-2\_en.pdf. (n.d.). In [https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-v-risk-management-systems-rev-2\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-v-risk-management-systems-rev-2_en.pdf).
- Health Canada. (2022, May 2). *Pharmaceutical drugs directorate.* Canada.ca. <https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/therapeutic-products-directorate.html>
- *Home.* (n.d.). CDSCO. <https://cdsco.gov.in/openems/openems/en/Home/>
- *Homepage.* (n.d.). European Medicines Agency. <https://www.ema.europa.eu/en/homepage>
- *ICH official web site : ICH.* (n.d.). ICH Official web site : ICH. <https://www.ich.org/page/efficacy-guidelines>
- (n.d.). MedDRA. <https://www.meddra.org/>
- (2023, September 26). U.S. Food and Drug Administration. <https://www.fda.gov/>

**Evaluation (PSBTY6501EL1): Total marks per course – 100.**

- Formative Assessment 'for' Learning.  
CIA- 40 marks (Project assignment)
- Summative Assessment 'of' Learning  
End Semester Examination – 60 marks.  
One question from each unit for 15 marks, with internal choice. Total marks per question with choice -20 to 22.

**Distribution of Bloom's Taxonomy levels for the course assessment**

Learning Levels	Remembering	Understanding	Analyzing and Application	Evaluation And creation
*Percentage	NA	30-35%	40-45%	20-30%



**Course Title: APPLICATIONS OF INFORMATICS IN BIOTECHNOLOGY**

**Course Code: PSBTY6501EL1**

**Credits 4: Theory 30 hrs and Practical 30 hrs**

No.	Course Objectives	
1.	The course aims to familiarize learners with the applications of informatics in various domains of Biotechnology.	
CO	Course Outcomes On completing the course, the learner will be able to	Bloom's Taxonomy Level (BT level)
1	Gain proficiency in using informatics tools and software applications relevant to immunological research	Understanding, Applying
2	Apply the principles of vaccine design and be able to apply informatics approaches to identify potential vaccine candidates, predict antigenic epitopes, and assess vaccine efficacy.	Understanding, Applying
3	Develop proficiency in using bioinformatics tools and software applications relevant to plant biology research	Applying
4	Gain a thorough understanding of the principles and concepts of nutrigenomics, including the interaction between nutrients and genes, and the impact of individual genetic variations on nutrient metabolism, absorption, and utilization.	Analyzing
5	Proficient in applications of AI and ML in healthcare settings, including disease diagnosis, medical imaging analysis, drug discovery, personalized treatment planning, predictive analytics, and health monitoring.	Analyzing Evaluating, Creating

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**APPROVED SYLLABUS**



<b>MSc II BIOTECHNOLOGY</b>		
<b>Course Title: APPLICATIONS OF INFORMATICS IN BIOTECHNOLOGY</b>		
<b>Course Code: PSBTY6501ELI</b>		
<b>Credits 4: Theory 30 hrs and Practical 30 hrs</b>		
<b>No.</b>	<b>Course Objectives</b>	
1.	The course aims to familiarize learners with the applications of informatics in various domains of Biotechnology.	
<b>CO</b>	<b>Course Outcomes On completing the course, the learner will be able to</b>	<b>Bloom's Taxonomy Level (BT level)</b>
1	Gain proficiency in using informatics tools and software applications relevant to immunological research	Understanding, Applying
2	Apply the principles of vaccine design and be able to apply informatics approaches to identify potential vaccine candidates, predict antigenic epitopes, and assess vaccine efficacy.	Understanding, Applying
3	Develop proficiency in using bioinformatics tools and software applications relevant to plant biology research	Applying
4	Gain a thorough understanding of the principles and concepts of nutrigenomics, including the interaction between nutrients and genes, and the impact of individual genetic variations on nutrient metabolism, absorption, and utilization.	Analyzing
5	Proficient in applications of AI and ML in healthcare settings, including disease diagnosis, medical imaging analysis, drug discovery, personalized treatment planning, predictive analytics, and health monitoring.	Analyzing Evaluating, Creating



<b>UNIT I</b>	<b>Data Resources for Immunoinformatics</b>		<b>16(T+P)</b>
	1.	Basic concept of immunology - Types of immunity, cells of immune system, epitope, paratope, Antigenicity, allergenicity	
	2.	Concept of Immunoinformatics, current trends in Immunoinformatics	
	3.	Immunological databases - Antibody databases, Allergenic Databases, Pathogen antibody databases, Monoclonal antibody databases, organism / pathogen specific immunology databases, Epitope databases, IMGT, IEDB, Databases related to molecule evolution of immune gene and proteins and other related resources.	
	4.	Computational tools in Immunoinformatics - Online tools for analysis of gene, and proteome data related to immune system.	
	5.	Immunomics - concept and applications	
<b>UNIT II</b>	<b>Vaccine Designing</b>		<b>16 (T+P)</b>
	1.	Epitope prediction - T and B cell	
	2.	Epitope analysis	
	3.	Allergenicity prediction	
	4.	Computational vaccine designing - Epitope prediction, docking, population coverage studies, Mapping of Vaccine Construct, Codon optimization and In Silico Cloning, Immune simulation, MD simulation.	
	5.	Structural studies - Antigen and antibody structural studies, modelling, and interaction studies	
<b>UNIT III</b>	<b>Plant Bioinformatics</b>		<b>14 (T+P)</b>
	1.	Bioinformatics databases and tools for plant biotechnology. Bioinformatics for plant breeding - examples - Rice, Maize. Bioinformatics for studying stress resistance in plants, Bioinformatics approaches to study resistance to plant pathogen (Case studies)	
	2.	Network pharmacology and applications - Network Biology to Network Pharmacology, Network Ethnopharmacology, Network pharmacology common databases network construction, case studies and applications.	



	3.	Nutrigenetics and Nutrigenomics: Concept of nutrigenetics, Nutrient- gene interactions, Nutrigenomics, Nutraceuticals, Natural bioactive compounds	
	4.	Biodiversity informatics: Biodiversity informatics: Concepts, practices, and challenges, Indian Biodiversity Information System (IBIS), Global Biodiversity Information Facility, Biodiversity Information Management, India Biodiversity Portal	
UNIT IV		<b>ML and AI in Biotechnology</b>	14 (T+P)
	1.	AI and ML concepts and models	
	2.	Overview of applications in biological sciences and biotechnology	
	3.	AI in Agricultural Biotechnology - AI-based algorithms in the agricultural sector	
	4.	Health Informatics <ul style="list-style-type: none"> <li>• AI in medical Biotechnology - AI in disease detection, Framework for AI in disease detection modelling, medical imaging for diseases diagnosis</li> <li>• AI in disease monitoring</li> <li>• AI and ML in Drug discovery - ML and AI in drug discovery, Role of ML in Predicting Drug Efficacy and Toxicity, Case Studies of Successful AI-Aided Drug Discovery, Challenges and Limitations</li> </ul>	

**Reference Books:**

1. Edwards, D. (Ed.). (2008). *Plant bioinformatics: methods and protocols* (Vol. 406). Springer Science & Business Media.
2. Flower, D. R. (Ed.). (2008). *Immunoinformatics: Predicting immunogenicity in silico* (Vol. 409). Springer Science & Business Media.
3. Krane, D. E. (2002). *Fundamental concepts of bioinformatics*. Pearson Education India.
4. Pevsner, J. (2015). *Bioinformatics and functional genomics*. John Wiley & Sons.
5. Tomar, N. (Ed.). (2020). *Immunoinformatics*. Humana Press.
6. Yang, Z. R. (2010). *Machine learning approaches to bioinformatics* (Vol. 4). World scientific.



**Research Articles:**

1. Bhardwaj, A., Kishore, S., & Pandey, D. K. (2022). Artificial intelligence in biological sciences. *Life*, 12(9), 1430.
2. Blanco-Gonzalez, A., Cabezon, A., Seco-Gonzalez, A., Conde-Torres, D., Antelo-Riveiro, P., Pineiro, A., & Garcia-Fandino, R. (2023). The role of ai in drug discovery: challenges, opportunities, and strategies. *Pharmaceuticals*, 16(6), 891.
3. Chandran, U., Mehendale, N., Patil, S., Chaguturu, R., & Patwardhan, B. (2017). Network pharmacology. *Innovative approaches in drug discovery*, 127.
4. Hopkins, A. L. (2008). Network pharmacology: the next paradigm in drug discovery. *Nature chemical biology*, 4(11), 682-690.
5. Johnson N. F. (2007). Biodiversity informatics. *Annual review of entomology*, 52, 421-438. <https://doi.org/10.1146/annurev.ento.52.110405.091259>
6. Noor, F., Tahir ul Qamar, M., Ashfaq, U. A., Albutti, A., Alwashmi, A. S., & Aljasir, M. A. (2022). Network pharmacology approach for medicinal plants: review and assessment. *Pharmaceuticals*, 15(5), 572.
7. Oli, A. N., Obialor, W. O., Ifeanyichukwu, M. O., Odimegwu, D. C., Okoyeh, J. N., Emechebe, G. O., & Ibeanu, G. C. (2020). Immunoinformatics and vaccine development: an overview. *ImmunoTargets and therapy*, 13-30.
8. Thomas, S., Abraham, A., Baldwin, J., Piplani, S., & Petrovsky, N. (2022). Artificial intelligence in vaccine and drug design. *Vaccine Design: Methods and Protocols, Volume 1. Vaccines for Human Diseases*, 131-146.

**Evaluation (PSBTY6502EL1):**

**Total marks per course – 100.**

- Formative Assessment 'for' Learning (continuous internal assessment - CIA to improve learning).  
CIA- 40 marks (Mini Project/ Assignment)
- Summative Assessment 'of' Learning (focus on outcomes, quantitative data for outcomes of instruction).  
End Semester Examination – 60 marks.  
One question from each unit for 15 marks, with internal choice. Total marks per question with choice -20 to 22.

**Distribution of Bloom's Taxonomy levels for the course assessment**

Learning Levels	Remembering	Understanding	Analyzing and Application	Evaluation	Creation
*Percentage	10%	25-35%	20-25%	15-20%	10-15%

