



**DOMBIVLI SHIKSHAN PRASARAK MANDAL'S,
K.V. PENDHARKAR COLLEGE OF ARTS, SCIENCE AND
COMMERCE, (AUTONOMOUS) DOMBIVLI (EAST), DIST. THANE
(Affiliated to University of Mumbai)**

Faculty of Science

**DEPARTMENT OF BIOTECHNOLOGY
(Programme: Masters of Science, M.Sc.)**

**SYLLABUS FOR
M.Sc. – Biotechnology (Semester III and IV) NEP-2020
Choice Based Credit System (CBCS)**

(With effect from the Academic Year: 2024-2025)

**Ms. Sandeeptha Rathindran
BoS Chairperson**

**Prof. (Dr.) K. R. Jagdeo
I/C Principal**

M.Sc. Biotechnology Part-II Course Structure

Semester- III

Sr. No.	Course code	Course Title	Category	Teaching hours/ week	Total Marks	Credits
1.	BT24301MM	Clinical Microbiology	Major Mandatory 1	4	100	4
2.	BT24302MM	Enzyme Technology	Major Mandatory 2	4	100	4
3.	BT24303MM	(Practical of Clinical Microbiology & Nanobiotechnology)	Major Mandatory 3	6	100	3
4.	BT24304MM	(Practical of Enzyme Technology & Nanobiotechnology)	Major Mandatory 4	6	100	3
5.	BT24305ME	Nanobiotechnology	Major Elective	4	100	4
6.	BT24306RP	Research Project	Research Project	8	100	4

Semester- IV

Sr. No.	Course code	Course Title	Category	Teaching hours/ week	Total Marks	Credits
1.	BT24401MM	Bioinformatics & Biostatistics	Major Mandatory 1	4	100	4
2.	BT24402MM	Biotechnology and Environment	Major Mandatory 2	4	100	4
3.	BT24403MM	Practical Paper (Practical of Bioinformatics & Biostatistics & Biotechnology and Environment)	Major Mandatory 3	8	100	4
4.	BT24404ME	Drug Discovery & Clinical Pharmacology	Major Elective	4	100	4
5.	BT24405RP	Research Project	Research Project	12	200	6

SEMESTER III

Course code	Course Title	Category	Credits
BT24301MM	CLINICAL MICROBIOLOGY	Major Mandatory 1	4

Course Objectives: To acquaint the students with the knowledge of pandemic diseases, significance of epidemiology, emerging viral, bacterial, parasitic pathogens and advanced methods for determining antimicrobial susceptibility, drug resistance and various aspects of biofilms.

Course Outcomes: By the end of the course, the student will be able to:

- Elaborate on the role of viruses in pandemic diseases and suggest diagnostic and treatment methods.
- Discuss the Epidemiological principles in prevention & control of disease.
- Outline the Organizations involved in disease control & research.
- Describe the pathogenesis clinical manifestations, diagnosis and treatment of bacterial, viral and parasitic infections.
- Summarize on the conventional and advanced methods of drug susceptibility testing.

Unit	Topics	Number of lectures
Unit I Viruses and Pandemic	Introduction to Pandemic diseases and causative agent like H1N1, MERS, SARS, Swine flu, COVID-19, Nipah virus, Ebola virus. Structure of these virus-coat and envelope protein, genome composition Pathogenesis (Mechanism of infection) and Acute Clinical manifestations (Signs and symptoms) of H1N1, MERS, SARS, Swine flu, COVID-19, Nipah virus, Ebola virus Diagnosis, and Treatment for H1N1, MERS, SARS, Swine flu, COVID-19, Nipah virus, Ebola virus Economic and Social loss due to Viruses	15
Unit II Epidemiology of infectious diseases	Concept of Host, Reservoir, Source of infection, Carrier, Epidemic, Endemic, Pandemic, Outbreak History, Definition scope, importance of epidemiology Epidemiology, Health & Public Health Epidemiological principles in prevention & control of disease Measures of disease frequency – Concept of incidence, prevalence, Incidence rate, cumulative incidence, case Fatality Epidemiological studies Organizations in disease control & Research – WHO, CDC, UNICEF, NACO, ICMR, NARI, NIV & NGOs	15
Unit III Pathogens and Emerging infections	Emerging Pathogens / Infections: Diseases caused by Bacteria / parasites/ viruses Name of causative agent, Name of disease caused, History, Antigenic structure, virulence factors, source of infection, Transmission, Pathogenesis, Clinical manifestations, Laboratory diagnosis, Treatment, Prophylaxis, vaccines, Current research and developments	15

	Bacteria as emerging pathogens / Diseases caused by bacteria: MOTT, Legionella, Conditions caused by <i>Helicobacter pylori</i> Viruses as emerging pathogens / Diseases caused by viruses: HIV (AIDS), Chikungunya, Dengue, Parasites as emerging pathogens / Diseases caused by parasites : Malaria , <i>Entamoeba histolytica</i> (Amoebic dysentery)	
Unit IV Biofilms & Antimicrobial Activity	Structure of Biofilm – Extracellular polymeric substances, Biofilm architecture. Stages in formation of Biofilm. Microbial interactions in Biofilms (Quorum sensing) Need for formation of Biofilms by Microorganisms Microorganisms commonly associated with biofilms on indwelling medical devices Response of biofilms to host defence mechanisms & antimicrobial agents Recent advances in biofilm management. Conventional methods of drug susceptibility testing Advanced methods- Macro & Micro broth dilution methods, Time kill curves, serum killing curves, checker-board assays. Detection of drug resistance in Staphylococci, Streptococci, Enterococci. Automated methods of sensitivity testing.	15

References:

1. Microbiology An introduction 10th edition Gerald Tortora, Burdell Funke, Christine Case, pearson Education Inc. Publication 2010
2. Basic Epidemiology R. Bonita, Bealglehole, T. Kjellstrom, 2nd Edition, 2006, WHO
3. Principles of Epidemiology in Public Health Practice, Third edition, US Department of Health & Human Services, CDC, 2012
4. Martin Rusnák, Viera Rusnáková, Georges Kamto, RELATIONS BETWEEN EPIDEMIOLOGY AND PUBLIC HEALTH, 2018 <https://www.researchgate.net/publication/323964710>
5. Evaluation and use of Epidemiological evidence for environmental health risk assessment guideline document World Health Organization 2000 eur/00/5020369
6. Ananthanarayan and Paniker's Textbook of Microbiology, by Reba Kanungo, 10th ed Universities Press; Tenth edition, 2017
7. Koneman's Colour Atlas & Textbook of Diagnostic microbiology, 7th edition, 2017, Lippincott, Williams & Wilkins.
8. Mackie & McCartney Medical Microbiology, J. G. Collee, J. P. Duguid, A. G. Fraser, B. P. Marmion, Thirteenth edition, Churchill Livingstone
9. Bailey and Scotts Diagnostic Microbiology Forbes, Sahem et al 12th ed, Moshby

Course code	Course Title	Category	Credits
BT24302MM	ENZYME TECHNOLOGY	Major Mandatory 2	4

Course Objectives: To make the students familiar with the basic concepts of enzymes like enzyme kinetics, techniques of enzyme purification, need for enzyme engineering and its benefits with applications, role of enzymes as a diagnostic tool and use of enzymes as Biosensors.

Course Outcomes: By the end of the course, the student will be able to:

- Elaborate on the techniques of enzyme purification.
- Describe the enzyme kinetics and the regulation of enzyme activity.
- Outline the applications of enzymes in diagnosis, therapy, industrial application and as biosensors.
- Discuss the outcomes of enzyme deficiencies.

Unit	Topics	Number of lectures
Unit I Introduction to enzymology	Brief history and introduction; chemical nature and properties of enzymes; mechanism of action of enzyme; catalytic power and specificity of enzymes; types of catalysis; enzyme kinetics, enzyme inhibition; enzyme specificity; regulation of enzyme activity; allosteric enzymes and their kinetic properties; units of enzymes; non protein enzymes; coenzymes and cofactors; isoenzymes	15
Unit II Enzyme purification and enzyme engineering	Techniques of enzyme purification: Based on molecular size, solubility of proteins and electric charge, adsorption properties Other techniques: Immobilized metal ion affinity chromatography, Hydrophobic interaction chromatography, Reversed phase chromatography and Chromatofocusing. Enzyme engineering – Introduction, Objectives, Principles, Examples and Steps involved in enzymes engineering. Applications of enzyme engineering.	15
Unit III Industrial & medical application of enzymes	Textile Industry, Detergent Industry, Pulp and Paper Industry, Animal Feed Industry Enzyme Technology for Detoxification of Mycotoxins in Animal Feed, Phytases for Feed Applications and Leather Industry. Enzyme Applications for Human and Animal Nutrition. Biosensors – Introduction, instrumentation, Types and examples. Enzymes based sensors as diagnostic tools- Biosensors for Blood Glucose, Biosensors for Urea in Blood and Urine, Biosensors for Uric Acid, Biosensors for Arginine, Biosensors for Asparagine, Biosensors for Creatinine,	15

	Biosensors for Cholesterol, Allosteric enzyme based biosensors.	
Unit IV Enzyme Deficiencies, diagnostic enzymes and therapeutics	Disorders of amino acid metabolism- Phenylketonuria, Alkaptonuria, Homocystinuria. Disorders of carbohydrate metabolism – Galactosemia, Hereditary fructose intolerance, Hereditary lactose intolerance. Disorder of lipid metabolism - Gaucher disease, Fabry disease. Disorders of purine and pyrimidine metabolism- HGPRT deficiency, Adenosine deaminase deficiency, Orotic aciduria. Enzymes in diagnosis of diseases- Liver disorders, Cancer, Cardiac disorders. Role of Other enzymes- Lysozyme, Butyrylcholinesterase and Lipases. Therapeutic uses of enzymes - enzymes in replacement therapy, enzymes in cancer treatment, enzymes for fibrinolysis, enzymes used for various treatments and enzyme gene therapy.	15

References:

1. Lehninger Principles of Biochemistry (4th Ed. Nelson, D., and Cox, M.; W.H. Freeman and Company, New York, 2005.
2. Satyanarayan and Chakrapani, Biochemistry. New Delhi, Elsevier Health Sciences APAC, 2013.
3. Berg JM, Tymoczko JL, Stryer L (2002): Biochemistry, 5th ed., Freeman WH and Co., New York.
4. https://shodhganga.inflibnet.ac.in/bitstream/10603/100595/7/07_chapter%201.pdf General Introduction to enzymes.
5. <https://iopscience.iop.org/book/978-0-7503-1302-5/chapter/bk978-0-7503-1302-5ch1> Introduction to enzymes and their applications.
6. Biochemistry by Lehninger, 2nd Ed, Kalyani publication 2008.
7. Understanding enzymes (3rd edition). Edited by Trevor Palmer, Ellis Horwood, Chichester, 1991.
8. Protein purification principles, High Resolution Methods, and Applications, 3rd Edition, Jan-Christer Janson, John Wiley & Sons, Inc., Hoboken, New Jersey.
9. <https://www.biotecharticles.com/Applications-Article/Methods-of-Purification-of-Enzymes-583.html>
10. https://www.creative-enzymes.com/service/enzyme-purification_307.html Enzyme Purification
11. http://web.sunghsin.ac.kr/~spark/class/enzchem/EnzChem_ch02.pdf Chapter 2 - purification of enzymes
12. <https://www.labome.com/method/Protein-Purification.html>
13. <http://www1.lsbu.ac.uk/water/enztech/index.html> Chapter 6 Enzyme preparation and use
14. <https://docplayer.net/20937505-Protein-purification-nison-sattayasai-khon-kaenuniversity-thailand-1-introduction-2-extraction-of-protein.html>
15. http://www.processdevelopmentforum.com/ppts/posters/Protein_purification_methods-overview,_29155460.pdf
16. https://www.researchgate.net/publication/281102215_How_to_purify_proteins.
17. Fundamentals of Enzyme Engineering, Young Je Yoo, Yan Feng, Yong-Hwan Kim, Camila Flor J. Yagonia, : Springer Netherlands 2017.

Course code	Course Title	Category	Credits	Number of lectures
BT24303MM	PRACTICAL PAPER 1 (Practical of Clinical Microbiology & Nanobiotechnology)	Major Mandatory 3	3	6

1. Viral Titering – Plaque Assay, Tissue Culture Infectious Dose (TCID), Chicken Embryo Infectious Dose (CEID)
2. Immunoassays: For detection of the virus antigens by ELISA / RIA
3. Diagnosis of dengue (kit method)
4. Antibiotics susceptibility testing by broth Macro dilution method & Micro broth dilution method
5. Study of microbial biofilm formation on various surfaces & Biofilm visualization by staining
6. Demonstration of minimum biofilm inhibition concentration of antibiotics/disinfectants.
7. Biosynthesis and characterization of eco-friendly silver nanoparticles by using plant/leaf extracts/green tea.
8. Synthesis and characterization of zinc sulfide nanoparticles by reverse micelle method.

Course code	Course Title	Category	Credit	Number of lectures
BT24304MM	PRACTICAL PAPER 2 (Practical of Enzyme Technology & Nanobiotechnology)	Major Mandatory 4	3	6

1. Microbial Enzyme production:
 - Partial purification using ammonium sulphate precipitation.
 - Dialysis of the salt-precipitated protein.
 - Assessing the enzyme activity and the protein content.
2. Effect of inhibitors/ chemicals on enzyme activity.
3. Extraction of enzymes from plant sources.
4. Measurement of Enzymatic Activity by Using a Colorimetric Assay.
5. Measuring Lactase Enzymatic Activity.
6. To determine Specific activity of α Amylase from different sources.
7. Synthesis and characterization of eco-friendly silver nanoparticles and its separation using the Thin-Layer Chromatographic Method
8. Synthesis of alginate beads and investigation of citric acid release from a nanoshell coating of polymer
9. Antimicrobial activity testing of Nanoparticles/nanocomposites.

Course code	Course Title	Category	Credits
BT24305ME	NANOBIOTECHNOLOGY	Major Elective	4

Course Objectives: To familiarize the students with the concept of nanotechnology and how it can be used to improve our everyday life, and also acquaint them with the knowledge of synthesis and applications of nanomaterials in the field of medicine and understanding of nanotoxicology.

Course Outcomes: By the end of the course, the student will be able to:

- Elaborate on the various applications of nanomaterials.
- Summarize on the types of nanomaterials and nanostructures found in nature.
- Discuss the role of nanotechnology in drug delivery.
- Give an account of the toxicity and factors responsible for the Nanomaterial toxicity.

Unit	Topics	Number of lectures
Unit I Overview of nanotechnology	Introduction: Nanotechnology, Nature's biological pathway, Examples of nanomaterials and nanostructures found in nature. Nanometer-scale materials: Nanometer-Scale Metals Nano Metal Oxides, Nanopolymers, Quantum Dots, Carbon nanostructures. Nanorobotics devices of nature ATP synthase, the kinesin, myosin, dynein, flagella modulated motion. Nanotechnology and Future Socioeconomic challenges	15
Unit II Synthesis of Nanomaterials	Synthesis of nanometer-scale materials- Top down and Bottom up approaches. Self-Assembly of nanoparticles and its mechanism. Bio-directed synthesis and assembly of nanomaterials Synthesis and Assembly of Nanoparticles and nanostructures Using Bio-Derived Templates	15
Unit III Nanotechnology in drug delivery	Biological Barriers to Nanocarrier- Mediated Delivery of Therapeutic and Imaging Agents, Nano-Sized Carriers for Drug Delivery, nano enabled drug delivery system, nanorobotics in medicine, Nanomedicine: biopharmaceutics, implantable materials, implantable chemicals, surgical aids Ethical issues in Nanobiotechnology with special reference to nanomedicine	15
Unit IV Applications of nanotechnology and Nanotoxicology	Applications of Nanomaterials. Nanotoxicology: Unique Properties, Toxicity of Nanomaterials, Factors Responsible for the Nanomaterial Toxicity, Routes of Exposure, Mechanisms of Nanoparticle Toxicity, In Vitro Testing Methods for Nanomaterials, Ecotoxicity Analyses of Nanomaterials	15

References:

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2. Guozhong, Cao. Nanostructures and nanomaterials: synthesis, properties and applications. World scientific, 2004.
3. Sulabha K. Kulkarni (auth.) - Nanotechnology_ Principles and Practices-Springer International Publishing (2015)
4. Crookes-Goodson, W. J., Slocik, J. M., & Naik, R. R. (2008). Bio-directed synthesis and assembly of nanomaterials. Chemical Society Reviews, 37(11), 2403-2412
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7. Chad A. Mirkin, Christof M. Niemeyer - Nanobiotechnology II_ More Concepts and Applications-Wiley-VCH (2007)
8. Oded Shoseyov, Ilan Levy NanoBioTechnology_ BioInspired Devices and Materials of the Future (2008, Humana Press)
9. Textbook of Nanoscience and Nanotechnology by B.S. Murty, P. Shankar, Baldev Raj, B B Rath, James Murday
10. Arun Kumar - Nanomedicine in drug delivery-CRC Press _ Taylor & Francis (2013).
11. Yuliang Zhao, Zhiyong Zhang, and Weiyue Feng - Toxicology of Nanomaterials-Wiley- VCH (2016)
12. Diwan, Parag, and Ashish Bharadwaj, eds. The Nanoscope: Encyclopedia of Nanoscience and Nanotechnology. Pentagon Press, 2005. (Vol 1-6)

SEMESTER IV

Course code	Course Title	Category	Credits
BT24401MM	BIOINFORMATICS & BIOSTATISTICS	Major Mandatory 1	4
<p>Course Objectives: To familiarize the students with the knowledge of specific databases and perform effective database searches, DNA sequence analysis, phylogenetic analysis and protein modelling tools. Also it will impart knowledge about data collection and biostatistical tools.</p> <p>Course Outcomes: By the end of the course, the student will be able to:</p> <ul style="list-style-type: none"> • Explain vast array of databases and their resources. • Apply tools of multiple sequence alignment and protein modelling. • Apply commonly used statistical methods and interpret their results. • Express hypothesis using various tools of biostatistics. 			
Unit	Topics	Number of lectures	
<p>Unit I Basics of Bioinformatics and DNA sequence analysis</p>	<p>Bioinformatics basics: Computers in biology and medicine; Database concepts; Protein and nucleic acid databases; Structural databases; databases and search tools: biological background for sequence analysis; Identification of protein sequence from DNA sequence; searching of databases similar sequence; NCBI; publicly available tools; resources at EBI; resources on web; database mining tools.</p> <p>DNA sequence analysis: gene bank sequence database; submitting DNA sequences to databases and database searching; sequence alignment; pairwise alignment techniques; motif discovery and gene prediction;</p>	15	
<p>Unit II Multiple sequence alignments and protein modelling</p>	<p>Multiple sequence alignment; flexible sequence similarity searching with the FASTA3 program package; use of CLUSTALW and CLUSTALX for multiple sequence alignment;</p> <p>Submitting DNA protein sequence to databases: SEQUIN, genome centres; submitting aligned sets of sequences, updating submitted sequences,</p> <p>Methods of phylogenetic analysis.</p> <p>Protein modelling: introduction, mapping properties onto surfaces, assigning secondary structures;</p> <p>Sequence alignment- methods, evaluation, scoring; protein completion: backbone construction and side chain addition; small peptide methodology; software accessibility; building peptides; protein displays</p>	15	

<p>Unit III Introduction to Biostatistics</p>	<p>Introduction and scope of statistics in biological studies and basic concepts. Collection of data, by different sampling methods Measures of central tendency Measures of Dispersion: Variance/ standard deviation, coefficient of variation and standard error. Confidence limits for mean and proportion. Probability and Basic concepts: Normal and binomial distribution. Correlation and regression analysis for a bivariate data: Scatter diagram</p>	<p>15</p>
<p>Unit IV Tools of biostatistics</p>	<p>Test of Hypothesis: Null hypothesis, alternate hypothesis, test statistics, Type I and Type II errors, level of significance and critical region. Z test: for a single sample, two samples and two sample proportion. t-test a single sample, two samples and testing the significance of the correlation. Coefficient: t paired test, x² test: As a goodness of fit and in 2x2 contingency test</p>	<p>15</p>

References:

1. Lesk, A. M. (2002). Introduction to Bioinformatics. Oxford: Oxford University Press.
2. Mount, D. W. (2001). Bioinformatics: Sequence and Genome Analysis. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press.
3. Baxevanis, A. D., & Ouellette, B. F. (2001). Bioinformatics: a Practical Guide to the Analysis of Genes and Proteins. New York: Wiley-Interscience.
4. Pevsner, J. (2015). Bioinformatics and Functional Genomics. Hoboken, NJ.: Wiley-Blackwell.
5. Bourne, P. E., & Gu, J. (2009). Structural Bioinformatics. Hoboken, NJ: Wiley-Liss.
6. Lesk, A. M. (2004). Introduction to Protein Science: Architecture, Function, and Genomics. Oxford: Oxford University Press.
7. S. P. Gupta, Statistical Methods, (45th Revised Edition), Publisher SCHAND
8. William G. Cochran, Sampling Techniques (3th Edition), Wiley and sons
9. Boris V. Gnedenko, Theory of Probability (6th Edition), CRC Press, 13-May-1998
10. Oscar Kempthorne, Klaus Hinkelmann, Design and Analysis of Experiments, Volume1: Introduction to Experimental Design, 2nd Edition, ISBN: 978-0-471-72756-9 December 2007
11. Acheson Johnston Duncan, Quality Control and Industrial Statistics (5th Edition), Irwin; 5 edition January 1, 1986
12. BK Mahajan, Methods in Biostatistics (7th Edition), Published December 1st 2008 by JP Medical Ltd

Course code	Course Title	Category	Credits
BT24402MM	BIOTECHNOLOGY AND ENVIRONMENT	Major Mandatory 2	4

Course Objectives: To make the students aware about the biotechnology based solutions for environmental issues, ethical and safety aspects of genetically modified products, concepts and strategies related to nutraceutical and functional foods production and applications.

Course Outcomes: By the end of the course, the student will be able to:

- Apply environmental quality evaluation, monitoring and remediation techniques.
- Summarize importance of carbon footprint and concept of environmental sustainability.
- Explain role of transgenic crops, nutraceuticals with its health benefits.
- Outline the need for biosafety and bioethical conflicts in biotechnology.

Unit	Topics	Number of lectures
Unit I Biotechnology in Environment Protection	Environmental pollution: urban aspects (biomedical waste, e-waste, solid waste) Environmental Monitoring: concepts, strategies, and applications of nanotechnology Biofouling and biodeterioration: agents and protection methods Bioremediation: Biodegradation and bioconversion of natural and xenobiotic compounds Phytoremediation overview, microbially assisted phytoremediation, genetic strategies for advancing phytoremediation potential in plants. Heavy Metal Bioremediation- conventional and advanced methods	15
Unit II Environmental sustainability	Concept of sustainability, carbon footprint and credits Biomass management Sustainability in agriculture: Bio-pesticides, Bio-fertilizers and Integrated Pest management Energy and Environment: Bioenergy Metagenomics: concept, strategies, and applications in environmental biotechnology	15
Unit III Transgenic crops and nutraceuticals	Transgenic crops-Bt based & others and fallacies associated, GM based phytonutrients Food security dilemma- GM food Vs Organic food Nutraceuticals and Functional Foods: Definition, characteristic features, and classification; Sources, Applications of nutraceuticals in human health and nutrition- health effects of commonly used nutraceuticals and functional foods, Safety and Regulatory guidelines	15

<p>Unit IV Biosafety and ethical conflicts</p>	<p>Biosafety- history, Need for containment and levels (microorganisms, plants and animals – both GMOs and LMOs), primary containment of biohazards, BSCs, Clean Room technology</p> <p>Regulatory guidelines: both national and International for food and food ingredients produced using GMOs, GM crops and livestock, Cartagena Protocol, Role of IBSC, RCGM, GEAC, and others</p> <p>Safety and Environment Impact concerns with respect to GMOs, LMOs, GM foods, Crops and Livestock, Risk assessment, management and communication including GMP, GLP, and HACCP, Generally, Recognised as Safe (GRAS) , Bioethical conflicts in Biotechnology: ELSI of HGP, Ethical concerns in GM utilized for consumption, agricultural benefits or human therapy.</p>	<p>15</p>
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References:

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2. Alan H. Scragg (2006) Environmental Biotechnology, 1 st edition, Oxford University Press
3. Alexander N. Glazer and Hiroshi Nikaido (2010) Microbial Biotechnology, 2nd edition, Cambridge University Press.
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11. S.K. Agarwal (2007) Environmental Biotechnology, APH Publishing Co-operation New Delhi
12. Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal.
13. Traavik. T and Lim Li Ching, (2007): Biosafety first. Tapir Academic Press

Course code	Course Title	Category	Credits	Number of lectures
BT24403MM	PRACTICAL PAPER (Practical of Bioinformatics & Biostatistics & Biotechnology and Environment)	Major Mandatory 3	4	8

1. Introduction and use of various genome databases.
2. Sequence information resource: Using NCBI, EMBL, Genbank, Entrez, Swissprot/ TrEMBL, UniProt.
3. Similarity searches using tools like BLAST and interpretation of results.
4. Multiple sequence alignment using ClustalW.
5. Phylogenetic analysis of protein and nucleotide sequences.
6. Using RNA structure prediction tools.
7. Use of different protein structure prediction databases (PDB, SCOP, CATH).
8. Measures of dispersion: Standard deviation for grouped and ungrouped data: standard value for the mean and proportion Confidence limits for the mean and proportion
9. Probability: Normal distribution and Binomial distribution use of normal tables
10. Correlation and Regression: Estimation of correlation coefficient, to fit regression equations from bivariate data
11. Test of hypothesis: a) Z-test, b) t-test c) x² test d) f-test
12. Bioremediation- isolation of metal tolerant organisms & study their growth characteristics and pattern.
13. Isolation of pesticide degraders.
14. Pollution indicators- Detection and Identification.
15. Soil ecosystem analysis/ analysis of microorganisms of soil.
16. Detection of heavy metals concentration in soil/ water .

Course code	Course Title	Category	Credits
BT24404ME	DRUG DISCOVERY & CLINICAL PHARMACOLOGY	Major Elective	4

Course Objectives: To provide the students' knowledge about Clinical Trial Design and Indian Regulations, Pharmacovigilance and the processes involved in manufacturing of biopharmaceuticals.

Course Outcomes: By the end of the course, the student will be able to:

- Discuss drug discovery-design pathway using in-silico tools.
- Elaborate on ADR and its mechanism.
- Outline the framework of clinical trials and summarize the roles and responsibilities of Stakeholders in the Sharing of Clinical Trial Data.
- Summarize the processes involved in manufacturing of biopharmaceuticals.

Unit	Topics	Number of lectures
Unit I Drug design and Development	Introduction to the drug discovery & development <ul style="list-style-type: none"> • Source of drugs • Structural effects on drug action • Drugs derived from natural products • General principles of pharmacology • Drug development and testing process Approaches to new drug discovery <ul style="list-style-type: none"> • Computer-aided drug design • Identification of novel drug candidates and drug targets • Construction of the signalling network of a drug using integer linear programming • Identification for druggable targets of a disease 	15
Unit II Clinical Trial Design and Indian Regulations	Clinical Trial Design <ul style="list-style-type: none"> • Basic framework of clinical trial • Randomized clinical trials and different phases • Adaptive randomization methods • Seamless design • Internal pilot design • Design selection factors Regulations <ul style="list-style-type: none"> • The national regulatory body • Key documents in clinical research • Regulatory requirements for the conduct of clinical trials in India The Roles and Responsibilities of Stakeholders in the Sharing of Clinical Trial Data <ul style="list-style-type: none"> • Participants in clinical trials, • Investigators, • Research institutions and universities • Journals and Professional societies 	15

<p>Unit III Pharmacovigilance</p>	<ul style="list-style-type: none"> • Scope and purposes of pharmacovigilance • Adverse Drug Reactions (ADR) • ADR classification • Nature and mechanism of ADR • Concept of safety • Phases and types of DATA <p>The process of Pharmacovigilance</p> <ul style="list-style-type: none"> • Signal detection, evaluation and investigation, • Communication <p>Methods of evaluating effectiveness of action</p> <p>International regulatory collaboration</p> <ul style="list-style-type: none"> • WHO, CIOMS, ICH, ISoP, ISPE 	<p style="text-align: center;">15</p>
<p>Unit IV Manufacturing of Biopharmaceuticals</p>	<p>Guides to good manufacturing practice: The manufacturing facility, Clean rooms, Cleaning, decontamination and sanitation (CDS), Water for biopharmaceutical processing</p> <p>Microbiological considerations and Excipients</p> <p>Delivery systems</p> <p>Product analysis: Protein-based contaminants, Removal of altered forms of the protein of interest from the product stream, Detection of protein-based product impurities, Immunological approaches to detection of contaminants, Endotoxin and other pyrogenic contaminants, Microbial and viral contaminants, Miscellaneous contaminants, Validation studies, Labelling and Packaging</p>	<p style="text-align: center;">15</p>

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- 2 Basic & Clinical Pharmacology, 2017, Fourteenth Edition, Section I, Chapter 1. Bertram G. Katzung, Editor ISBN 978-1-259-64115-2 MHID 1-259-64115-5 ISSN 0891-2033
- 3 Software based approaches for drug designing and development: A systematic review on commonly used software and its applications, Bulletin of Faculty of Pharmacy, Cairo University 55 (2017) 203–210 Prasad G. Jamkhande, Mahavir H. Ghante, Balaji R. Ajgunde <http://dx.doi.org/10.1016/j.bfopcu.2017.10.001>
4. Bioinformatics and Drug Discovery, Third Edition, (A Computational Platform and Guide for Acceleration of Novel Medicines and Personalized Medicine, Chapter 10) Richard S. Larson, Tudor I. Oprea <https://doi.org/10.1007/978-1-4939-9089-4>
5. Clinical Trial Designs, Indian Dermatol Online J. 2019 Mar-Apr; 10(2): 193–201. Brijesh Nair doi: 10.4103/idoj.IDOJ_475_18 PMID: PMC6434767
6. Regulatory requirements for clinical trials in India: What academicians need to know, Indian J Anaesth 2017;61:192-9 Nithya J Gogtay, Renju Ravi, Urmila M Thatte DOI: 10.4103/ija.IJA_143_17 PMID: 30984604
7. Regulatory environment for clinical research: Recent past and expected future, Perspect Clin Res 2017;8:11-6. Bhave A, Menon S DOI: 10.4103/2229-3485.198551
8. An Introduction to Pharmacovigilance, Second Edition *Patrick Waller and Mira Harrison-Woolrych* ISBN 9781119289753 (Adobe PDF)

Evaluation pattern M.Sc. Part II Biotechnology (Autonomous) 2024 -2025

The examination of 100 marks per Theory Paper for each course will be conducted in the pattern of 40 marks of internal assessment/Project work and 60 marks for Semester end examination. The student will have to secure a minimum of 40% marks in the Internal assessment and Semester end examination per theory paper.

The Semester examinations of 100 marks per Practical Paper at the end of each semester will be conducted. The student will have to secure a minimum of 40% marks in the examination per practical paper.

In M.Sc Part-II Semester III and Semester IV, the students will have to undergo Research project in any subject related laboratories, companies or research institutions.

OR

The Project work will be carried out by the student with the guidance of the concerned Faculty Member who will be allotted the student as the Guide for the Project.

Evaluation Pattern for M.Sc. Biotechnology Part II (Theory)

1.	INTERNAL ASSESSMENT		40 Marks
1.1	One class test (Objectives/ Multiple Choice)		20 Marks
1.2	Assignment/ Project/ Presentation/Book or Research paper review report/Business proposal presentation/Case-study		15 Marks
1.3	Active Participation, Overall performance		05 Marks
2.	EXTERNAL ASSESSMENT (Semester End Examination)		60 Marks
	N.B. 1. All questions are compulsory 2. All questions carry equal marks.		
	Q.1.	Based on Unit-I, II, III & IV Multiple choice questions/Fill in the blanks /Match the column/Give one word/Name the following/Give an example/Explain the term/Define/Give significance/State the role of/ State True or false.	12
	Q.2.	Unit-I Long Answer Question Short Answer Question	12 12/08/06 04/02
	Q.3.	Unit-II Long Answer Question Short Answer Question	12 12/08/06 04/02

	Q.4.	Unit-III Long Answer Question Short Answer Question	12 12/08/06 04/02
	Q.5	Unit-IV Long Answer Question Short Answer Question	12 12/08/06 04/02

Evaluation Pattern
M.Sc Biotechnology Part II (PRACTICAL)

1.	EXTERNAL ASSESSMENT	100 Marks
	Experiment –1(Major technique)	25
	Experiment –2 (Major technique)	25
	Experiment -3 (Minor technique)	15
	Experiment -4 (Minor technique)	15
	Viva/ Identification	10
	Journal	10
	TOTAL MARKS	100
