SCHEME & SYLLABUS OF
VII & VIII SEMESTERS
(160 Credits)

NEP I (2021-2025)

VISION AND MISSION OF THE DEPARTMENT

VISION:

To be a center of excellence in education and research in Biotechnology to address the global challenges

MISSION:

1. To offer industry relevant curriculum and research through industry collaborations.
2. To continuously upgrade the infrastructure to develop the facilities for training and research.
3. To provide a good learning environment to help students imbibe professional ethics, communication skills, team spirit and societal commitment.

PROGRAM EDUCATIONAL OBJECTIVES (PEOS)

The Program Educational Objectives are as follows:

1. The graduates of the program are practicing engineering profession in IT sectors (IT system engineers, data analyst and computer programmer), and BT sectors (clinical data coordinator, clinical research associate, Quality controller and Quality assurance analyst, Molecular biologist and Business development executive)
2. The graduates of the program are engaged in higher studies leading to professional degree in specific domain such as biological sciences, computational biology and also engaged in life-long learning.
3. The graduates of the program practice profession with high ethical and moral values and have developed good communication skills and leadership qualities while working as a member of the team or as a team leader.

PROGRAM SPECIFIC OUTCOMES (PSOs):

- Students will be able to conduct the Upstream and Downstream experiments to produce, optimize, separate, purify and characterize biological compounds.
- Students will be able to solve advanced biological problems with the technical skills of Bioinformatics, Biomolecular simulation, Proteomics and Genomics using computational techniques.

- Students will be able to analyse Biopharmaceutical challenges of Biological systems by applying the concepts of Biological sciences

PROGRAMME OUTCOMES (POs)

PO1	**Engineering Knowledge:** Apply knowledge of mathematics, natural science, computing, engineering fundamentals and an engineering specialization respectively to develop to the solution of complex engineering problems.
PO2	**Problem Analysis:** Identify, formulate, review research literature and analyze complex engineering problems reaching substantiated conclusions with consideration for sustainable development.
PO3	**Design/Development of Solutions:** Design creative solutions for complex engineering problems and design/develop systems/components/processes to meet identified needs with consideration for the public health and safety, whole-life cost, net zero carbon, culture, society and environment as required.
PO4	**Conduct Investigations of Complex Problems:** Conduct investigations of complex engineering problems using research-based knowledge including design of experiments, modelling, analysis & interpretation of data to provide valid conclusions.
PO5	**Engineering Tool Usage:** Create, select and apply appropriate techniques, resources and modern engineering & IT tools, including prediction and modelling recognizing their limitations to solve complex engineering problems.
PO6	**The Engineer and The World:** Analyze and evaluate societal and environmental aspects while solving complex engineering problems for its impact on sustainability with reference to economy, health, safety, legal framework, culture and environment.
PO7	**Ethics:** Apply ethical principles and commit to professional ethics, human values, diversity and inclusion; adhere to national & international laws.
PO8	**Individual and Collaborative Team work:** Function effectively as an individual, and as a member or leader in diverse/multi-disciplinary teams.
PO9	**Communication:** Communicate effectively and inclusively within the engineering community and society at large, such as being able to comprehend and write effective reports and design documentation, make effective presentations considering cultural, language, and learning differences.
PO10	**Project Management and Finance:** Apply knowledge and understanding of engineering management principles and economic decision-making and apply these to one's own work, as a member and leader in a team, and to manage projects and in multidisciplinary environments.
PO11	**Life-Long Learning:** Recognize the need for and have the preparation and ability for i) independent and life-long learning ii) adaptability to new and emerging technologies and iii) critical thinking in the broadest context of technological change.

SIDDAGANGA INSTITUTE OF TECHNOLOGY, TUMAKURU

(An autonomous institution affiliated to VTU, Belagavi, Approved by AICTE, New Delhi, Accredited by NAAC with 'A' grade & ISO 9001:2015 Certified)

B.E. in BIOTECHNOLOGY

03.10.2024

VII Semester **SCHEME OF TEACHING AND EXAMINATION (160 Credits Scheme) (NEP-I)**

Sl. No.	Course and Course Code		Course Title	Teaching / Paper setting Dept.	Teaching hrs/week				Examination				Credits
					Lecture	Tutorial	Practical/ Drawing	TW+ SL Component	Duration in hrs.	CIE Marks	SEE Marks	Total Marks	
					L	T	P	S					
VII Semester													
1.	PCC	N7BT01	Enzyme Technology	BT	42	-	-	48	3	50	50	100	3
2.	PEC	N7BTPEXX	Professional Elective Course-II	BT	42	0	0	48	3	50	50	100	3
3.	PEC	N7BTPEXX	Professional Elective Course-III	BT	42	0	0	48	3	50	50	100	3
4.	OEC	OEXX	Open Elective Course-II	Any Dept	42	0	0	48	3	50	50	100	3
5.	AEC	N7CCA01	Research Methodology & Intellectual Property Rights	BT	28	-	-	32	3	50	50	100	2
6.	Project	N7BTP1	Project Work	BT	Monday to Thursday shall be marked for carrying out Project work				3	50	50	200	10
							280	20					
			Total		196		280	244		**350**	**350**	**700**	**24**
		AAP	AICTE Activity Points	40 hours community service to be documented and produced for the examination									
VIII Semester													
1.	Seminar	BTTS	Technical Seminar	BT	One contact hour /week for interaction between the faculty and students.					100	--	100	1
2.	Internship	INT3	**INTERNSHIP – III** (Research/Industry Internship)	BT	Two contact hours /week for interaction between the faculty and students.					100	100	200	15
										200	**100**	**300**	**16**
		AAP	AICTE Activity Points							**100**	**---**	**100**	**0**

Professional Elective -II		**Professional Elective -III**	
N7BTPE21	Forensic Science	**N7BTPE31**	Clinical Trials and data Management
N7BTPE22	Biomaterials and Medical Implant	**N7BTPE32**	Genomics & Proteomics
N7BTPE23	Computer Aided Drug Design	**N7BTPE33**	Biosimilars
N7BTPE24	Biopharmaceuticals and Regulatory affairs	**N7BTPE34**	Green Biotechnology and Pollution Abatement

Note: **PCC**: Professional Core Course, **PEC**: Professional Elective Course, **OEC** –Open Elective Course, **AEC** –Ability Enhancement Course

L –Lecture, **T** – Tutorial, **P**- Practical/ Drawing, **S** – Self-Study Component, **CIE**: Continuous Internal Evaluation, **SEE**: Semester End Examination **TW + SL**: Term Work and Self learning.

VIII Semester

SCHEME OF TEACHING AND EXAMINATION (160 Credits Scheme) (NEP-I)

PROJECT WORK (BTP): The objective of the Project work is

(i) To encourage independent learning and the innovative attitude of the students.

(ii) To develop interactive attitude, communication skills, organization, time management, and presentation skills.

(iii) To impart flexibility and adaptability.

(iv) To inspire team working.

(v) To expand intellectual capacity, credibility, judgment and intuition.

(vi) To adhere to punctuality, setting and meeting deadlines.

(vii) To instill responsibilities to oneself and others.

(viii) To train students to present the topic of project work in a seminar without any fear, face the audience confidently, enhance communication skills, involve in group discussion to present and exchange ideas.

CIE procedure for Project Work:

(1) **Single discipline:** The CIE marks shall be awarded by a committee consisting of the Head of the concerned Department and two senior faculty members of the Department, one of whom shall be the Guide. The CIE marks awarded for the project work, shall be based on the evaluation of Project Work Report, Project Presentation Skill, Question & Answer session and Guide Assessment in the ratio 40:20:20:20. The marks awarded for the project report shall be the same for all the batch mates.

(2) **Interdisciplinary:** Continuous Internal Evaluation shall be group-wise at the college level with the participation of all guides of the project. Participation of external guide/s, if any, is desirable. The CIE marks awarded for the project work, shall be based on the evaluation of Project Work Report, Project Presentation Skill, Question & Answer session and Guide Assessment in the ratio 40:20:20:20. The marks awarded for the project report shall be the same for all the batch mates.

SEE procedure for Project Work:

SEE for project work will be conducted by the two examiners appointed by the Chairman-BoE. The SEE marks awarded for the project work, shall be as per the Table mentioned below:

Project Report	25
Presentation & Demonstration	30
Quality of Work	25
Viva-Voce (Q&A Session)	20
Total	**100**

Note: VII and VIII semesters of IV year of the programme

(1) Departments can swap VII and VIII Semester Scheme of Teaching and Examinations to accommodate research internship/ industry internship after the VI semester.

(2) Credits earned for the courses of VII and VIII Semester Scheme of Teaching and Examinations shall be counted against the corresponding semesters whether VII or VIII semester is completed during the beginning of IV year or later part of IV year of the programme.

TECHNICAL SEMINAR (BTTS):

The objective of the seminar is to inculcate self-learning, present the seminar topic confidently, enhance communication skill, and involve in group discussion for exchange of ideas. Each student, under the guidance of a Faculty, shall choose, preferably, topic of his/her interest relevant to the programme of Specialization.

(i) Carry out literature survey, systematically organize the content.

(ii) Prepare the report with own sentences, avoiding a cut and paste act.

(iii) Type the matter to acquaint with the use of Micro-soft equation and drawing tools or any such facilities.

(iv) Present the seminar topic orally and/or through PowerPoint slides.

(v) Answer the queries and involve in debate/discussion.

(vi) Submit a typed report with a list of references.

The participants shall take part in the discussion to foster a friendly and stimulating environment in which the students are motivated to reach high standards and become self-confident.

Evaluation Procedure:

The CIE marks for the seminar shall be awarded by Department Seminar Evaluation Committee DSEC (based on the relevance of the topic, presentation skill, participation in the question-and-answer session, and quality of report) by the committee constituted for the purpose by the Head of the Department. The committee shall consist of three teachers from the department with the senior-most acting as the Chairman.

Marks distribution for CIE of the course is as shown in Table below:

Relevance of the topic	10 marks
Report	20 marks
Presentation	30 marks
Viva-Voce	20 marks
Guide Assessment	20 marks
Total	**100 marks**

No SEE component for Technical Seminar.

Non-Credit Mandatory Course (NCMC):

National Service Scheme/Physical Education (Sport and Athletics)/Yoga:

(1) Securing 40 % or more in CIE, 35 % or more marks in SEE and 40 % or more in the sum total of CIE + SEE leads to successful completion of the registered course.
(2) In case, students fail to secure 35 % marks in SEE, they have to appear for SEE during the subsequent examinations conducted by the University.
(3) In case, any student fails to register for NSS, PE or Yoga/fails to secure the minimum 40 % of the prescribed CIE marks, he/she shall be deemed to have not completed the requirements of the course. In such a case, the student has to fulfill the course requirements during subsequent semester/s to earn the qualifying CIE marks.
(4) Successful completion of the course shall be indicated as PP in the grade card. Non-completion of the course shall be indicated as NP.
(5) These courses shall not be considered for vertical progression as well as for the calculation of SGPA and CGPA, but completion of the courses shall be mandatory for the award of degree.

AICTE Activity Points:

Apart from technical knowledge and skills, to be successful as professionals, students should have excellent soft skills, leadership qualities and team spirit. They should have entrepreneurial capabilities and societal commitment. In order to match these multifarious requirements, AICTE has created a unique mechanism of awarding minimum 100 Activity Points for regular students and 75 Activity Points for Lateral Entry students over and above the academic grades.

The activities can be spread over entire duration of the programme and it will be reflected in the Student's VIII Semester Grade Card. It shall not be considered for computation of SGPA/CGPA and for vertical progression. The total duration of the activities for entire programme is 320 hours for regular students and 240 hours for lateral entry students.

Break-up of CIE marks for activity points:

Evaluation by the Proctor	50 marks
Evaluation by DSEC	
(i) Report	20 marks
(ii) Presentation	20 marks
(iii) Outcome	10 marks
Total	**100 marks**

1. No SEE for AICTE Activity Points.
2. Students will be awarded either NP or P grade based on marks obtained. 3. Students will be awarded 'Degree' only on earning P grade in the Activity Points.

ENZYME TECHNOLOGY

Contact Hours/ Week:	: 3+0+0 (L+T+P)	**Credits:**	3
Total Lecture Hours:	: 42	**CIE Marks:**	50
Sub. Code:	: N7BT01	**SEE Marks:**	50

Course objectives: This course will enable students to:	
1.	Understand the classification of enzymes and factors affecting enzyme action such as apoenzyme, prosthetic group, and co-factors.
2.	Learn the regulation of enzymes and its production.
3.	Study different catalysis of enzyme reactions and protein engineering.
4.	Understand the clinical use of enzymes.
5.	Learn the applications of enzymes in the industries.

UNIT I

Introduction to Enzymes: History of Enzymology: Nomenclature and International classification of enzymes; Holoenzyme, Apoenzyme, Cofactor, Coenzyme, Prosthetic group; Enzyme Activity Unit, Turn Over number and other catalytic Biomolecules. Isozymes and Allosteric Enzymes, Biological Roles of enzymes Activation Energy of enzymes, Chemical nature of enzymes, Active Sites of enzyme and identification of Functional Groups at active sites, Conceptual Numericals.

7 Hours

UNIT II

Enzyme Regulation: Feedback Regulation, Allosteric Regulation, Reversible, Covalent Modification and Proteolytic Activation. Enzymes in the cell, localization, enzymes in membranes, concentrations. Mechanisms of enzyme degradation, lysosomal and non-lysosomal pathways, examples.

Strategies used for Enzyme Production: Isolation and Purification, Characterization of an Enzymes. Determination of the Molecular Weight (Mr) and the Number of Sub-Units of an enzyme, Immobilization of Enzymes: Concepts, Different Methods of Immobilization, Characterization of Immobilized Enzymes and Application of Immobilized Enzymes.

8 Hours

UNIT III

Enzyme Catalysis and Inhibition: Mechanism of enzyme catalysis- Acid-base catalysis, covalent catalysis, Metal ion catalysis, Proximity and orientation effects etc., mechanism of Serine Proteases-Chymotrypsin, Lysozyme, Carboxypeptidase A.

Mechanism of Action of Enzymes without Cofactors (Lysozyme and Glyceraldehydes 3-Phosphate Dehydrogenases), Mechanism of action of enzymes with Cofactors / Coenzymes, Conceptual Numericals.

Enzyme Engineering & its applications: Enzyme-catalyzed peptide synthesis: enzymatic conversion of porcine into human insulin,Artificial Enzymes: Surface-Modified & Chemically Modified Enzymes, Design and construction of novel enzymes.Protein engineering of enzymes: Site directed mutagenesis,

9 Hours

UNIT IV

Clinical uses of Enzymes: Clinical enzymes- Enzymes as thrombolytic agents, Anti-inflammatory agents, streptokinase, asparaginase, Isoenzymes like CK and LDH, Transaminases (AST, ALT), Amylases, Cholinesterases, Phosphatases. Immobilization of enzymes, ELIZA. Biosensors. Enzyme Engineering and site directed mutagenesis, Designer enzymes.

8 Hours

UNIT V

Industrial use of enzymes (Applied Enzymology): Industrial Enzymes, cheese making and brewing. Thermophilic enzymes, amylases, lipases, proteolytic enzymes in meat and leather industry, enzymes used in various fermentation processes, cellulose degrading enzymes, Metal degrading enzymes.

10 Hours

TEXT BOOKS

1	Nicholas C. Price and Lewis Stevens	Fundamentals of Enzymology: Oxford University Press,3rd edition, 2010, 9780198552970
2	N S Punekar	Enzymes: Catalysis, Kinetics and Mechanisms, Springer, 2018, 978-981-13-0784-3

REFERENCE BOOKS

1	Dixon, M and Webb E.C	Enzymes, Academic Press, New York, 1997, 9781483225609, 3rd Edition,
2	Guo Yong	Enzyme Engineering, Springer, 2014, 978-1842657638, 3rd edition

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Describe the classification of enzymes, chemical nature, enzyme activation and its biological roles.
CO2	Analyze the regulation and immobilization strategies of enzyme.
CO3	Analyze the mechanism of catalysis and enzyme engineering.
CO4	Apply the strategies for production and clinical use of enzymes
CO5	Identify the applications of enzymes in industries.

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Program Articulation Matrix

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
N7BT01	2	2												2

Mapping Of Course Outcomes (COs) To Program Outcomes (POs) & Program Specific Outcomes (PSOs)

		POs											PSOs		
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**1**	**2**	**3**
COs	**CO1**	2	1												2
	CO2	2	2												2
	CO3	2	1												2
	CO4	2	1												2
	CO5	2										1			2

1: Low, 2: Medium, 3: High

FORENSIC SCIENCE

Contact Hours/ Week:	: 3+0+0 (L+T+P)	**Credits:**	3
Total Lecture Hours:	: 42	**CIE Marks:**	50
Sub. Code:	: N7BTPE21	**SEE Marks:**	50

Course objectives: This course will enable students to:	
1.	Learn the history, development and different areas of forensic science
2.	Understand the documentation, collection of physical evidence & classification of forensic laboratories
3.	Study the types of courts & understand the scope of anthropology
4.	Know about forensic toxicology & pathology
5	Learn about genetics and ethics of forensic science

UNIT I
Forensic Science: Definition and Scope, special areas of Forensic science-pathology, toxicology, anthropology, odontology, engineering, biology, geology, psychiatry, questioned documents, criminalistics, jurisprudence etc. History and Development of Forensic science. Examination of dead & living cases. Crime scene investigation, Medico legal investigation, Colonial Period, The Republic, The Twentieth Century, New York System, California, European Developments in Criminalistics, American Developments in Criminalistics structure of evidence.
9 Hours

UNIT II
Crime lab: Introduction to documentation & collection of physical evidence, Types of physical evidence-Body fluids, Body tissues, Drugs and controlled substances, Fibers, Finger, palm, and footprints, Fire and explosive materials, Firearms and projectile stools, Glass, Hair, Oils and grease or cosmetic products, Paint and paint products-separating complete mixtures, light microscopy. Classification of Laboratories, Typical Sections of the Forensic or Crime Laboratory, Toxicology and Drug Identification, Arson Analysis-Steam distillation, Solvent extraction, Cold head space, Heated headspace, Vapor concentration on charcoal. Typical selections of forensic or crime lab-

Toxicology & drug identification, firearms & tool marks, trace evidence, fingerprint identification, forensic photography submitting evidence.
8 Hours

UNIT III
Scientific evidence in court: Types of courts**:** Equitable, Admiralty, Law, Coroner, Grand Jury, State and Federal. Types of courts of law-civil &criminal.Evidence Testamentary and Demonstrative or Physical, Types of Testamentary Witnesses, Fact Witnesses, Expert Witnesses, Hypothetical Questions, Role of the Judge Legal medicine &jurisprudence: investigating systems, medico-legal issues, forensic expert, education & employment. Scope of anthropology: Introduction, identification of Forensic taphonomy, demographic characteristics of skeleton. Personal identification, facial imaging, facial reconstruction, photographic comparison.
8 Hours

UNIT IV
Forensic pathology: Rigor mortis, Algor mortis. Forensic Anthropology, Forensic Entomology, Forensic Psychiatry, Forensic Odontology, Forensic Engineering, DNA Analysis, Dactyloscopy, Finger prints: Classification and patterns.Forensic toxicology: History of Forensic Toxicology Deaths investigated by toxicologists,Accidental Poisoning, Deaths from Drug Abuse, suicidal Poisoning, Homicidal Poisoning, Toxicological Investigation of a Poison Death, toxicological analysis, types of poisons -Gases, Steam Volatile Poisons, Metallic Poisons,Nonvolatile Organic Poisons, Miscellaneous Poisons & types of tests-Color Test, Micro diffusion Test.
8 Hours

UNIT V
Forensic Genetics: DNA typing, serology-Physical Properties of Blood, blood stain pattern interpretation, Angle of Impact, Points of Convergence, Point of Origin, Low-Velocity Bloodstain Patterns, Medium-Velocity Bloodstain Patterns, High-Velocity Bloodstain Patterns biological analysis of body fluids, genetic markers, DNA finger print profile, autoradiogram, PCR technology, RFLPs, VNTRs, biological material collection, characterization & storage.Ethics in Forensics:The importance of professional ethics to science practitioners, Development of code of conduct and code of ethics for forensic science.

	9 Hours

TEXT BOOKS		
1	The synopsis of Forensic Medicine and Toxicology	KS Narayan Reddy, Mahender Reddy, Jaypee Brothers Medical Publishers Pvt Ltd, Elsevier 2022, 1st edition, 90789389776218
2	An introduction to Forensic genetics	William Goodwin, Adrian Linacre, Sibte Hadi, Wiley 2010, 2nd Edition

REFERENCE BOOKS		
1	Hand book of Forensic services	An FBI laboratory publication, 2015

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Apply the forensic science in various fields and discuss the associated regulatory aspects
CO2	Describe the laboratory set-up and process for a criminal investigation
CO3	Identify the court process and scope of anthropology
CO4	Identify the type of death according to the toxicity
CO5	Assess thetechniques associated with the forensic genetics and associate with the forensic ethics

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Program articulation matrix

Course	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**
N7BTPE21	2	1		1	2	1	1	1			1			1

Mapping of Course Outcomes (COs) to Program Outcomes (POs) & Program Specific Outcomes (PSOs)

		POs											PSOs		
		1	2	3	4	5	6	7	8	9	10	11	1	2	3
COs	CO1	2	1				1	1							1
	CO2	2	1		1				1						1
	CO3	2	1					1							1
	CO4	2	1					1							1
	CO5	2				2						1			1

1: Low, 2: Medium, 3: High

BIOMATERIALS AND MEDICAL IMPLANTS

Contact Hours/ Week:	: 3+0+0 (L+T+P)	**Credits:**	3
Total Lecture Hours:	: 42	**CIE Marks:**	50
Sub. Code:	: N7BTPE22	**SEE Marks:**	50

Course objectives: This course will enable students to:	
1.	Learn the basics of biomaterials and its properties
2.	Understand the concept of design of synthetic biomaterials
3.	Gain knowledge in the implantable devices and its usage
4.	Know the application of biomaterials in cardiovascular diseases
5.	Learn the biocompatibility studies related to biomaterials

UNIT I
Biomaterials: Historical developments, definition and classification of biomaterials, impact of biomaterials, mechanical properties, wound healing process, tissue response to implants, safety and efficiency testing, bio-compatibility. Metallic and Ceramic Biomaterials: Stainless steel, cobalt chromium alloys, titanium-based alloys, nitinol, metallic corrosion, medical applications, biological tolerance of implant metals. Case studies.
9 Hours

UNIT II
Synthetic polymers: Relatively bioinert bioceramics, biodegradable ceramics, surface reactive or bioactive ceramics, composites-polymer and nanocomposites, analysis of ceramic surfaces, deterioration of ceramics, medical applications, Nano-composites. Synthetic and Biopolymers: Polymers in biomedical use, biodegradable synthetic polymers, silicone rubber, plasma polymerization, microorganism in polymeric implants, bio polymers, polymer sterilization. Case studies.
8 Hours

UNIT III
Implantable devices: Implantable Cardiovascular Assist Devices, Artificial RBC Substitutes, Orthopedic Applications, Dental Implants, Adhesives and Sealants, Ophthalmological Applications (Various types of contact lenses, IntraOcular Lens Implant), Cochlear Prostheses. Case studies.
8 Hours

UNIT IV
Cardiovascular biomaterials: Tissue properties of blood vessels, Treatments of atherosclerosis; Biomechanical design issues pertaining to stents, balloon angioplasty, and pacemakers. Soft Tissue Reconstruction; Natural and Synthetic. Wound healing. Tissue ingrowths: Stability; Biofixation, Foreign Body response, Soft implants. Case Studies. Tissue Engineering: Current issues and Future Directions. Case studies.
9 Hours

UNIT V
Biocompatibility: Wound healing process-bone healing, tendon healing. Material response: Function and Degradation of materials in vivo. Host response: Tissue response to biomaterials, Testing of bone implants: Methods of test for biological performance- In vitro implant tests, Qualification of implant materials. Case studies.
8 Hours

TEXT BOOKS		
1	J. B. Park and R. S. Lakes	An Introduction to Biomaterials, Springer, 2007, 978-0-387-37879-4

REFERENCE BOOKS		
1	J. Black	Biological Performance of materials: Fundamentals of Biocompatability, Routledge Taylor & Francis, 2006, 9780429126420

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Express the biological, mechanical and material aspects related to biomaterials.
CO2	Characterize the biological and mechanical properties of different types of synthetic polymers
CO3	Classify the types of implants with emphasis on their construction and functionality
CO4	Explain the construction and functionality of differenttypes of cardiovascular implants
CO5	Identify the advantages and disadvantages of materials in terms of its compatibilities, biological responses, and degradation

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Program Articulation Matrix

Course	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**
N7BTPE22	2	1				1	1				1			2

Mapping Of Course Outcomes (COs) To Program Outcomes (POs) & Program Specific Outcomes (PSOs)

	POs												PSOs		
		1	2	3	4	5	6	7	8	9	10	11	1	2	3
COs	CO1	2													1
	CO2	1	1				1	1							2
	CO3	2	2				2					1			2
	CO4	2	1				1					1			1
	CO5	1						1							2

1: Low, 2: Medium, 3: High

COMPUTER AIDED DRUG DESIGN

Contact Hours/ Week:	: 3+0+0 (L+T+P)	**Credits:**	3
Total Lecture Hours:	: 42	**CIE Marks:**	50
Sub. Code:	: N7BTPE23	**SEE Marks:**	50

Course objectives: This course will enable students to:	
1.	Study the basics of in-*silico* drug design and computer assisted lead molecule design
2.	Understand the role of molecular recognition in drug discovery process
3.	Study the molecular simulation and dynamics of biomolecules
4.	Learn how to identify potential lead compounds.
5.	Understand different approaches in *silico* drug design.

UNIT I
In*silico* Drug Design and Computer Assisted New Lead Design: Drug design and discovery: an overview. Introduction, historical perspective, drug compounds, preparation and organization for drug seeking, common stages in the drug seeking campaign, sources of hits, leads and candidate drugs, Natural products: higher plant and animal products, combinatorial libraries, Lead optimization. Introduction, Basic Concepts, Molecular Recognition by Receptor and Ligand Design, Active Conformation, Approaches to Discover New Functions, Approaches to the Cases with known and unknown receptor structure, Introduction to drug metabolism, toxicity and pharmacokinetics, toxicology considerations, problems and drawbacks on drug discovery and development, ADMET properties
9 Hours

UNIT II
Role of molecular recognition in drug design: Introduction, thermodynamic considerations of drug binding, physical basis of intermolecular interactions: enthalpic contributions, entropic contributions, total energy of intermolecular interactions, estimating individual group components in ligand-receptor interactions and co-operativity, rules of thumb.
8 Hours

UNIT III
Molecular Modeling and Simulation: Basic principles of molecular modeling, Steps in molecular modeling - Constructing an Initial Model, Refining the Model, Manipulating the Model, Visualization. Structure Generation or Retrieval, Structure Visualization, Conformation Generation, Deriving Bioactive Conformations, Molecule Superposition and Alignment, Deriving the Pharmacophoric Pattern, Receptor Mapping, Estimating Biological Activities, Molecular Interactions: Docking, Calculation of Molecular Properties, Energy Calculations (no derivation),Examples of Small Molecular Modeling Work, Nicotinic Ligands, Sigma Ligands, Antimalarial Agents and Basic principles of molecular dynamics simulation techniques. Types of programs available for molecular modeling-scope and limitations-interpretation of results.
8 Hours

UNIT IV
Stereochemistry in drug design: Introduction, stereoisomer, origin of stereospecificity in molecular recognition, importance of stereochemistry in drug design, methods of obtaining pure stereoisomer: resolution of racemates by crystallization of diastereomers, enantioselective chromatography, analytical methods of determining purity of stereoisomer: optical rotation, NMR spectroscopy, gas chromatography, capillary electrophoresis, mass spectroscopy.
9 Hours

UNIT V
Design and applications of prodrugs: The prodrug concept: definition, barriers to drug action, prodrug design in an industrial setting. Choice and function of the pro-moiety: cleavability of the prodrug bond, modification of physicochemical properties, macromolecular transport vectors. Bioreversible derivatives for various functional groups: Esters as a prodrugs for compounds containing carboxyl or hydroxyl groups, prodrugs for amides, imides and other NH-acidic compounds, prodrugs for amines, carbonyl groups, drug activation from intermolecular cyclization reactions, cyclic prodrugs involving two functional groups of

the drug, applications of prodrug.
8 Hours

TEXT BOOKS		
1	Povl Krogsgaard and Larsen	Molecular modelling, Multivista Global Ltd., 1st Edition, 2002, 978-0298789424
2	Andrew R Leach	Applied Computer-Aided Drug Design: Models and Methods, Igor José dos Santos Nascimento, Bentham books, 2023, 978-981-5179-93-4, 1st edition

REFERENCE BOOKS		
1	Ben Leimkuhler, C Matthews	Molecular Dynamics, Springer International publishing, 3rd Edition, 2015, 978-0298129456

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Describe the process of *In Silico* drug design and computer assisted lead design.
CO2	Analyze the inter-molecular interaction and role of molecular recognition in drug design
CO3	Describe the steps involved in molecular modeling and simulation
CO4	Analyze the methods of determining the stereo-chemistry in drug design.
CO5	Apply the principles of pro drug design and its application in various pharmaceutical industries.

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Program articulation matrix

Course	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**
N7BTPE23	2	2											2	

Mapping of Course Outcomes (COs) to Program Outcomes (POs) & Program Specific Outcomes (PSOs)

		POs											PSOs		
		1	2	3	4	5	6	7	8	9	10	11	1	2	3
COs	CO1	2	1											2	
	CO2	2	1											2	
	CO3	2	2											2	
	CO4	2	2											2	
	CO5	2	2											2	

1: Low, 2: Medium, 3: High

BIOPHARMACEUTICALS AND REGULATORY AFFAIRS

Contact Hours/ Week:	: 3+0+0 (L+T+P)	**Credits:**	3
Total Lecture Hours:	: 42	**CIE Marks:**	50
Sub. Code:	: N7BTPE24	**SEE Marks:**	50

Course objectives: This course will enable students to:	
1.	Study the basic concepts of biopharmaceuticals and understand the various system used as expression system.
2.	Understand the necessities of drug manufacturing process.
3.	Learn the concepts of vaccine production and antisense technology.
4.	Study the concepts of clean room and its importance in manufacturing pharma products.
5.	Understand the importance of regulatory affairs in pharma industry

UNIT I
Biopharmaceuticals: Introduction to Biopharmaceuticals and pharmaceutical biotechnology, History of the pharmaceutical industry, the age of biopharmaceuticals, Biopharmaceuticals: Status and future prospects, Traditional pharmaceuticals of biological origin. Sources of biopharmaceuticals: *E.coli* as a source of recombinant, therapeutic proteins, Expression of recombinant proteins in animal cell culture system. Host-Vector Interactions in *E.coli,* parameters influencing the productivity of Recombinant *E.coli* Cultivations. Additional production systems: yeasts, fungal production systems, transgenic animals, transgenic plants, Insect cell-based systems. Production of final product, cell banking systems, upstream processing, microbial cell fermentation. Mammalian cell culture systems.
8 Hours

UNIT II
The drug manufacturing process: The manufacturing facility: Clean rooms, cleaning, decontamination and sanitation (CDS), CDS of the general manufacturing area, water for biopharmaceutical processing, generation of purified water and water for injections (WFI), distribution system for WFI. **The drug development process:** Drug discovery: The impact of genomics and related technologies upon drug discovery,Gene chips, Proteomics, Structural genomics, Pharmacogenetics. Plants as a source of drugs: Microbial drugs,Rational drug design, Combinatorial approaches to drug discovery, Initial product characterization. Delivery of biopharmaceuticals: Oral delivery systems, Pulmonary delivery, Nasal, transmucosal and transdermal delivery systems.
8 Hours

UNIT III
Vaccines: Vaccine technology–Traditional vaccine preparations (attenuated, dead or inactive bacteria; attenuated and inactivated viral vaccines); Toxoids, antigen-based and other vaccine preparations; The impact of genetic engineering on vaccine technology – peptide vaccines and Vaccine vectors; Development of an AIDS vaccine and difficulties associated with vaccine development; Cancer vaccines. Nucleic acid and therapeutics: Gene therapy-basic approach, vectors used in gene therapy (Retroviral vectors, manufacture of viral vectors), Gene therapy and genetic disease. Anti-sense technology – antisense oligonucleotides, uses, advantages and disadvantages of 'Oligos', delivery and cellular uptake of oligonucleotides.
8 Hours

UNIT IV
Cleanroom: What is a Cleanroom? The Need for Clean rooms, Types of Cleanrooms, What is Cleanroom Technology? Basis of Clean room Standards, Federal Standard 209. Airborne Particle Counters, Measurement of Particle Concentrations (IS0 14644- 1) - Sample locations and number, Airborne sampling volume, Acceptance criteria, Microbial Counts - Microbial Sampling of the Air - Impaction onto agar, Microbial Deposition onto Surfaces, Microbial Surface Sampling – Contact surface sampling, Swabbing, Personnel sampling Operating a Clean room: Contamination Control - Identification of Sources and Routes of Contamination - Sources of contamination. Clean room Disciplines, Clean room Clothing, Routes and Sources of Microbial Dispersion, Types of Clean room clothing.
9 Hours

UNIT V
Quality life cycle: Introduction; Good laboratory practice (GLP) -GLP in Europe, GLP in the UK, GLP in the USA; Good clinical practice (GCP) - GCP in the USA, GCP in Europe, ICH guidelines on GCP, Good manufacturing practice (GMP); Good distribution practice (GDP). Quality assurance and control - Introduction; Relationship between quality management, QA, GMP and QC; Definition of quality management; Definition of quality assurance; Definition of quality control; Responsibilities of QA –QA requirements in EU, PIC/S, WHO, and FDA; Responsibilities of QC. Quality systems: ISO 9000 series; ISO 14000 series. Good manufacturing practice - Definition of GMP; Different versions of GMP (UK, European Union, USA, Australia, WHO, Arab World); Responsibilities under GMP; Rules versus guidelines. Good distribution practice - Principles of GDP; Digitalization: The Route to Biopharma 4.0, Indian Regulatory bodies
9 Hours

TEXT BOOKS		
1	Gary walsh	Biopharmaceuticals- Biochemistry and Biotechnology, Wiley-Blackwell, 2nd Edition, 2003, 978-0470843277.

REFERENCE BOOKS		
1	W Whyte	Clean Room Technology – Fundamentals of Design, Testing and Operation, John Wiley and Sons, 1st Edition, 2010, 978-0470858387.
2	G. Walsh, B. Murphy	Biopharmaceuticals, an Industrial Perspective, Springer Netherlands, 1st Edition, 2010, 978-9048152377.

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Classify different types of expression system and outline the production of biopharmaceutical products.
CO2	Explain the various requirements of drug manufacturing process and highlight the importance of drug development process.
CO3	Discuss various methods of vaccine production and interpret the concepts of gene therapy and antisense technology in treating human diseases.
CO4	Outline the requirement of cleanroom facilities, implementation of ISO standards in pharmaceutical industry
CO5	Summarize various regulatory bodies, quality control and quality assurance in biopharmaceutical industry

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Program articulation matrix

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
N7BTPE24	2	2												2

Mapping of Course Outcomes (COs) to Program Outcomes (POs) & Program Specific Outcomes (PSOs)

		POs											PSOs		
		1	2	3	4	5	6	7	8	9	10	11	1	2	3
COs	CO1	2	1												2
	CO2	2	1												2
	CO3	2	2												2
	CO4	2	2												2
	CO5	2	2												2

1: Low, 2: Medium, 3: High

CLINICAL TRAILS AND DATA MANAGEMENT

Contact Hours/ Week:	: 3+0+0 (L+T+P)	**Credits:**	3
Total Lecture Hours:	: 42	**CIE Marks:**	50
Sub. Code:	: N7BTPE31	**SEE Marks:**	50

Course objectives: This course will enable students to:	
1.	Impart knowledge in principles and practices of clinical trials and basic concepts in Ethical issues in research
2.	Get an understanding about what clinical research are and how they are classified and conducted
3.	Study the recruitment and regulations procedure of subjects for the clinical study
4.	Study the rolesand responsibilities of Investigator, Clinical research associate, Clinical coordinator and Data manager in executing the trials
5.	Study the various stages of clinical trials design, project management, resource management and data handling

UNIT I
Clinical Trails: Introduction to Clinical Trials: scope of clinical trial, clinical trials Phases, Phase I studies; Phase II studies; Phase III/IV studies. Introduction to ethics of Clinical Trials. Study Population: Definition of study population, Issues on generalization. History of clinical trials, Basic principles, Clinical trial, designing clinical trial: Planning steps (Develop a hypothesis for research, Define the objectives and Establishment, Define the variables needed, Define the study population, finalize the objective into testable hypothesis Predict error and bias, Selection of appropriate study design, Determination of sample size), Execution steps: Data collection process, Data entry, management and Publication.
9 Hours

UNIT II
An introduction to Biostatistics: Introduction: General Considerations; Clarity, comparability and Generalizability. Randomization; Randomization techniques, Simple randomization, block randomization, Stratified randomization.Issues in randomization: Reasons for randomization, types of randomized studies, alternative to randomized studies. Study objective; study design. Blinding: types of studies classified on the basis of blinding, methods of achieving double blinding. Sample size: measurements scale, statistical significance. Overview of Hypothesis testing: the goals of statistical inference, basic concepts in hypothesis testing.
8 Hours

UNIT III
Informed Consent Process: Introduction, the history of informed consent and the system of subject protection, Basic principles; autonomy, beneficence, and justice. Informed consent process, preparing the informed consent document- for adults and pediatrics, checklist, ensuring readability of the informed sheet and the consent form, special considerations. Role of CRC and CRA in clinical trials : The clinical research associate and coordinator, who can be a CRC/CRA, the sites where CRC/CRA works, responsibilities; general responsibilities; capacity building, trial related responsibilities; site identification, pre-trial documentation, IRB, regulatory, financial, administrative, training of the site staff, informed consent forms, site initiation visit, investigators meeting screening and recruitment, scheduling of visit, accountability, laboratory, monitoring. Skills of being a good CRC/CRA; watch, listen, document and report.
8 Hours

UNIT IV
Data Management in Clinical Research: Introduction: Overview of Clinical Data Management (CDM), Kinds of Data, Data Management plan, Data capture and collection: Paper CRF based study, Data Privacy. CRF Design: Paper based and electronic based CRF process, CRF login and inventory. Clinical Database. Data entry: double entry, single entry. Data Review and Validation: Point by Point Checks, Missing Data or blank field Checks, Data consistency Checks, Laboratory Data and range Checks, Discrete value group dispensary Checks, Header Inconsistency Checks, Missing page Checks and CRF tracking, Protocol validation Checks, continuity Data Checks, coding checks, external data Checks, textual Data Checks, SAE Reconciliation Checks. Discrepancy Management (brief), Database closure, Quality assurance, Data storage and archival, recent advances in CDM.
9 Hours

UNIT V
Literature Survey and Research Proposal Writing: Library sources; search engines, databases, search strategies, limiting the search using logical operators, broadening the search, sensitivity and specificity of literature searches, finding references for evidence- based practice, review and abstracts for evidence- based practice. Research Proposal: Introduction, working plan for developing a research proposal; the research plan (title, abstract, statement of the research problem, statement of the purpose of the study, method, literature cited, documentation of informed consent), plan for administrative support (budget; personnel, equipment, facilities and suppliers, resources and environment, personnel; qualifications, time commitment, job descriptions, consultant). Protocol review and grant approval: brief of protocol review and funding by National Institute for Health.
8 Hours

TEXT BOOKS		
1.	S.K Gupta	Basic Principles of Clinical Research and Methodology, JPB Publishers, 1st Edition, 2007, 978-0128499054
2.	Leslie Gross Portney, Mary P. Watkins	Foundations of Clinical Research: Applications to Practice, 4th edition, 2015, F. A. Davis Company

REFERENCE BOOKS		
1	Shein-Chung Chow, JenPei Liu	Design and Analysis of Clinical Trials : Concepts and Methodologies, John Wiley publications,2013 1st Edition,

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Outline the clinical trial process by defining the various clinical parameters
CO2	Enumerate the different statistical parameters related to clinical trails
CO3	Describe the roles of regulatory bodies and clinical coordinators for conducting the clinical trails
CO4	Relate the various documentations with the clinical data management system
CO5	Illustrate the Literature Review process and Research Proposal processes.

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Program articulation matrix

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
N7BTPE31	2	3	1		1	1	1	1	1	1		1		1

Mapping of Course Outcomes (COs) to Program Outcomes (POs) & Program Specific Outcomes (PSOs)

		POs											PSOs		
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**1**	**2**	**3**
COs	**CO1**	1		1			1					1	1		1
	CO2	2				2		1							1
	CO3	2						1							
	CO4	2						1							
	CO5	2	3	1		1		1	1	1	1	1	1		1

1: Low, 2: Medium, 3: High

GENOMICS AND PROTEOMICS

Contact Hours/ Week:	: 3+0+2 (L+T+P)	**Credits:**	4
Total Lecture Hours:	: 42	**CIE Marks:**	50
Sub. Code:	: N7BTPE32	**SEE Marks:**	50

Course objectives: This course will enable students to:	
1.	Grasp the concepts of chromosome content, gene localization within the genome, and the roles of non-coding and repetitive DNA segments in the context of genomics.
2.	Gain a deep understanding of advanced DNA sequencing techniques and related concepts essential for executing genome projects.
3.	Develop a comprehensive understanding of protein sequencing techniques and the use of mass spectrometry for protein identification in proteomics.
4.	Gain a thorough understanding of various techniques used for protein identification and expression analysis in quantitative proteomics
5.	Understand the bioinformatics techniques for analyzing genomics and proteomics data using computational tools and algorithms.

UNIT I
Introduction to Genomics: Major Differences between Eukaryotic, Bacterial and Archaea chromosomes. General features of the Eukaryotic genome and chromosomes. C value paradox, organization of eukaryotic genomes into chromosomes. Analysis of chromosomes using Genome Browser, BioMart. Analysis of chromosomes by the ENCODE project (scope and conclusions). Eukaryotic genome (noncoding and repetitive DNA sequence, Transposon derived repeats). Gene content of eukaryotic chromosomes, finding genes in eukaryotic genomes.
8 Hours

UNIT II
Genome Sequencing & Genome Projects:DNA sequencing methods: Sanger dideoxy method, Maxam Gilbert method, Automated Fluorescence method. Introduction to Next Generation Sequencing technology (NGS). Significant applications of NGS technologies. Comparison of NGS technologies with Sanger sequencing. Workflow of NGS experiments (from experimental design to analysis) – the experimental design and sample preparation, generating sequence data to FASTQ analysis and Genome assembly. Software: FASTQC and velvet. Genome analysis: Main types of genome analysis: Denovo sequencing,sequencing, transcriptome and epigenetics. Large scale –model organism sequencing projects: 1001 genome project, genome 10k project
8 Hours

UNIT III
Introduction to Proteomics: Structural Organization of Proteins. Proteomics: introduction, basic principles of proteomics. The origin and scope of proteomics. Proteomics and the new biology. Overview of analytical proteomics. Evolution from protein chemistry to proteomics. Protein sequencing and techniques: Protein sequencing by Edman technique. Molecular biology techniques- mass spectrometry techniques. Mass spectrometry-based methods for protein identification: Proteomics approaches: The bottom-up approach and top-down methods. Steps involved in proteomics. Ionization techniques: MALDI and ESI: Concepts, principles and methodology.
8 Hours

UNIT IV
Mass spectrometry: Basic principles and instrumentation. Schematic representation of a mass spectrometer. Mass analysers, ion trap and LTQ orbitrap. Quantitative proteomics and protein modifications: Protein quantification: Introduction, types of quantification, principles, and methodology. Isobaric tagging for relative and absolute quantitation (iTRAQ), Tandem mass tag (TMT), stable isotope labelling by amino acids in cell
9 Hours

UNIT V
Bioinformatics analysis of genomics and proteomics data: Concepts of Genomic and proteomics data, file formats, public databases, analyzing genome and proteome data. Functional analysis of genomics and proteomics data: GO term identification and enrichment analysis, pathway analysis, analysis of protein-protein-interactions. Protein domain and motif analysis.
9 Hours

TEXT BOOKS		
1	Richard M. Twyman	Principles of Proteomics, Garland Science, 2nd Edition, 2008, 978-0133779421
2	Devarajan Thangadurai, Jeyabalan Sangeetha	Genomics and Proteomics, 978-981-5179-93-4, Apple Academic Press Inc, 978-1771881142, 2015, 1st edition

REFERENCE BOOKS		
1	S.B. Primrose and R.M.Twyman	Principles of Genome analysis and Genomics, Blackwell Publishing, 3 rd Edition, 2003, 978 1405101202
2	Gibson G & Muse SV	A Primer of Genome Science, Sinauer Associates, 2 nd Edition, 2004, 978-1025101156

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Describe the concepts of chromosome content, gene localization within the genome, and the functions of non-coding and repetitive DNA segments in genomics.
CO2	Apply the advanced DNA sequencing techniques and related concepts for executing genome projects.
CO3	Illustrate protein sequencing techniques and apply the concept of mass spectrometry for protein identification in proteomics.
CO4	Apply various techniques used for protein identification and expression analysis in quantitative proteomics.
CO5	Develop proficiency in bioinformatics techniques for analyzinggenomics and proteomics data using computational tools and algorithms.

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Course	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**
N7BTPE32	2	2											2	

Program Articulation matrix Mapping of course outcomes with program outcomes

		POs											**PSOs**		
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**1**	**2**	**3**
COs	**CO1**	2	1											2	
	CO2	2	1											2	
	CO3	2	2											2	
	CO4	2												2	
	CO5	2	2											2	

1: Low, 2: Medium, 3: High

BIOSIMILARS

Contact Hours/ Week:	: 3+0+0 (L+T+P)	**Credits:**	3
Total Lecture Hours:	: 42	**CIE Marks:**	50
Sub. Code:	: N7BTPE33	**SEE Marks:**	50

Course objectives: This course will enable students to:	
1.	Recognize the difference between biosimilar and biologics, their regulatory challenges.
2.	Acquire knowledge about various types of biological compounds as biosimilar drugs.
3.	Analyze the various method of characterizing biosimilarmolecules.
4.	Apply the concepts of immunology and study the effects of biosimilars.
5.	Understand the role of Biotech companies in the production of biosimilar products.

UNIT I
Biopharmaceuticals: Generics in Biopharma, definition of biologics, biosimilars, super biologics, differences between chemical genetics and biosimilar, The developmental and regulatory challenges in biosimilar development, Prerequisites for Biosimilar development, Biosimilar market potential.
8 Hours

UNIT II
Biosimilar drugs: Peptides, proteins, antibodies, Enzymes, Vaccines, Nucleic acid-based therapies (DNA, RNA, etc), Cell based therapies (including stem cells). Case study of Semglee, Rezvoglar, Amjevita, Inflectra, Renflexis, Avsola, Truxima, Riabni, and Kanjinti
8 Hours

UNIT III
Characterization methods: Aggregation- precipitation, floccule strength, precipitate ageing & kinetics, adsorption of proteins & peptides on surfaces, effect of temperature on protein structure, hydration & thermal stability of proteins - solid powders, suspension on non-aqueous solvents, reversed micelles, aqueous solution of polyols,

analytical and spectrophotometric characterization of proteins, protein sequencing and structure determination.
10 Hours

UNIT IV
Bioequivalence studies: Immunogenicity & allergenicity of biosimilars; factors affecting immunogenicity - structural, post-translational modifications, formulations, impurities, manufacturing and formulation methods for biosimilars; types of bioequivalences (average, population, individual), experimental designs & statistical considerations for bioequivalence studies (non-replicated designs – General Linear Model, Replicated crossover designs), introduction to "ORANGE BOOK" & "PURPLE BOOK".
8 Hours

UNIT V
Case studies: Indian companies working in this space & their product pipeline (Biocon, Intas, Dr Reddy's, Reliance, Bharat Biotech,Lupin, Cipla, Shanta); products - Erythropoietin, growth hormone, granulocyte stimulating factors, interferons - Rebif, streptokinase, monoclonal antibodies - traztuzumab.
8 Hours

TEXT BOOKS		
1	Laszlo Endrenyi, Paul Declerck and Shein-Chung Chow,	Biosimilar Drug Development, Drugs andPharmaceutical Sciences, CRC Press, 1st Edition, 2017
2	Cheng LiuandK. John Morrow Jr.,	Biosimilars of Monoclonal Antibodies: A Practical Guide to Manufacturing, Preclinical and Clinical Development, Wiley, 1st Edition, 2016

REFERENCE BOOKS		
1	Karen M. Nagel	Introduction to Biologic and Biosimilar Product Development and Analysis, Springer International Publishing, 1st Edition, 2019

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Explain the concepts of similar and biosimilars and their associated regulatory policies
CO2	Differentiate between the working mechanisms of different types of biosimilars
CO3	Evaluate the various method of characterizing biosimilar molecules.
CO4	Describe the various biological compatibility factors of the biosimilars
CO5	Elucidate the role of Biotech companies in the production of biosimilar products.

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Program articulation matrix

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
N7BTPE33	2	2												2

Mapping of Course Outcomes (COs) to Program Outcomes (POs) & Program Specific Outcomes (PSOs)

		POs											PSOs		
		1	2	3	4	5	6	7	8	9	10	11	1	2	3
COs	CO1	2	1												2
	CO2	2	1												2
	CO3	2	2												2
	CO4	2	2												2
	CO5	2	2												2

1: Low, 2: Medium, 3: High

GREEN BIOTECHNOLOGY AND POLLUTION ABATEMENT

Contact Hours/ Week:	: 3+0+0 (L+T+P)	**Credits:**	3
Total Lecture Hours:	: 42	**CIE Marks:**	50
Sub. Code:	: N7BTPE34	**SEE Marks:**	50

Course objectives: This course will enable students to:	
1.	Recognize the various global and regional environmental concerns due to natural causes and/or human activities, and the impact of these on various forms of life including native biodiversity.
2.	Understand the physiology of a microorganism and how their structure dictates their function in the environment.
3.	Enable students to acquire comprehensive knowledge of environmental biotechnological processes for wastewater treatment, bioremediation and metal recovery.
4.	Understand the basis for microbial metabolism of environmental contaminants and to know the various techniques to modify and augment microorganisms in the laboratory and environment.
5.	Understand the principles of composting and Phytoremediation

UNIT I
Bioremediation: Definition, approaches to bioremediation, environmental modification, microbial seeding. Bioengineering approaches to the bioremediation of pollutants – engineering of bioremediation processes – needs and limitations. Xenobiotics, biodegradation of lignin, hydrocarbons, plastic.
8 Hours

UNIT II
Bioremediation of contaminated soils: Diversity and magnitude of soil contaminants, criteria for bioremediation, biological mechanism of transformation, strategies for bioremediation, Case studies of bioremediation. Biodegradable organic pollutants - Pesticides, aerobic and anaerobic bacteria degradation, cometabolic degradation, degradative capacities of fungi.
8 Hours

UNIT III
Bioremediation of various ecosystems: Bioremediation of contaminated water (oil slicks, heavy metals), bioremediation of industrial wastes - distillery-processes and production in the distillery, characteristics of effluent and treatment, textile industry- source and origin of dyes, characteristics of effluent, Environmental impact of dyes and its

intermediates and treatment, leather – processes and production, characteristics of effluent, Environmental impact of tannery effluents and treatment, paper and pulp manufacturing industries, Processes and production.
9 Hours

UNIT IV
Bioremediation Techniques: Bioaerosols, Biofiltration, microbial control of environmental pollution –role of genetic engineering in environmental pollution abatement, catabolic plasmids as natural vectors, genetic engineering of genes for augmenting pollution abatement in microbes and plants, use of immobilized microbes for waste recycling, immobilized enzymes in pollution abatement.
8 Hours

UNIT V
Composting and Phytoremediation: Exploitation of agricultural wastes for food, feed and fuel, humus formation, sludge composting, vermi composting, aerobic and anaerobic composting. Introduction to phytoremediation, phytoextraction, phytostabilization, phytoremediation of inorganics, translocation mechanisms for inorganics, plant accumulation.
9 Hours

TEXT BOOKS		
1.	Indu shekhar Thakur	Environmental Biotechnology, Basic concepts and Applications, I K International Publishing House Pvt. Ltd 2nd Edition, 2013, 9380578474.

REFERENCE BOOKS		
1	D. K. Maheshwari and R. C. Dubey	Bioremediation of Pollutants Hardcover IK International Publishing House Pvt. Ltd; 1st Edition, 2012, 9381141053.
2	Pradipta Kumar Mohaptra	Text book of Environmental Biotechnology, I K International Pvt. Ltd. 1st edition, 2013, 818823754X

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Describe the various methods of bioremediation of xenobiotics.
CO2	Explain the biological mechanism of transformation of xenobiotics in various environmental conditions.
CO3	Discuss the different types of treatment for industrial effluents.
CO4	Recognize and apply genetic engineering practices in environmental biotechnology.
CO5	Illustrate the application of microbes and plants in treating solid waste management as well as heavy metals.

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Course	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**
N7BTPE34	2	2	2	3	2	2		2	3	2				2

Program Articulation matrix Mapping of course outcomes with program outcomes

		POs											**PSOs**		
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**1**	**2**	**3**
COs	**CO1**	2	2			2									2
	CO2	2	2			2									2
	CO3		2	2		2									2
	CO4		2	2		3									2
	CO5				3	3	2		2	3	2				2

1: Low, 2: Medium, 3: High

RESEARCH METHODOLOGY AND IPR

Contact Hours/ Week:	2+0+0 (L+T+P)	**Credits:**	2
Total Lecture Hours:	28	**CIE Marks:**	50
Sub. Code:	N7CCA01	**SEE Marks:**	50

Unit-I
Introduction: Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations
6 Hours

Unit-II
Research Problem: Effective literature studies approaches, analysis Plagiarism, and Research ethics.
5Hours

Unit-III
Technical Writing: Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee
5Hours

Unit-IV
Intellectual Property Rights: Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: Technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.
6 Hours

Unit-V
Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.
6 Hours

TEXT BOOKS:		
1.	Wayne Goddard and Stuart Melville	Research methodology: an introduction, 2nd Edition, 2014, Juta AcademicLt.D. ISBN 9780702156601.
2.	Stuart Melville and Wayne Goddard	Research methodology: an introduction for science & engineering students, 2nd Edition, Juta Academic,
3.	Ranjit Kumar	Research Methodology: A Step by Step Guide for beginners, SAGE Publications India Pvt Ltd, 4th Edition, 2023, ISBN: 9789351501336

REFERENCE BOOKS:		
1.	T. Ramapp	Intellectual Property Rights Under WTO", S. Chand, 2008
2.	Robert P. Merges, Peter S. Menell, Mark A. Lemley	Intellectual Property in New Technological Age", 2016.

Course Outcomes: Upon completion of this course the student will be able to:	
CO1	Identify based on the knowledge the basics of research and its types.
CO2	Apply knowledge to write Literature Review, Technical Reading, Attributions and Citations.
CO3	Practice the knowledge of Ethics in Engineering Research
CO4	Apply the concepts of Intellectual Property Rights in engineering
CO5	Apply IPR knowledge for the granting patents and its procedure for new innovative product for grants.

CORRELATION BETWEEN COURSE OUTCOMES WITH PROGRAM OUTCOMES

Program articulation matrix

Course	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PSO1**	**PSO2**	**PSO3**
N7CCA01	3	3	3		2						3			

Mapping of Course Outcomes (COs) to Program Outcomes (POs) & Program Specific Outcomes (PSOs)

		POs											PSOs		
		1	2	3	4	5	6	7	8	9	10	11	1	2	3
COs	CO1	3	3	3		2						3			
	CO2	3	3	3		2						3			
	CO3	3	3	3		2						3			
	CO4	3	3	3		2						3			
	CO5	3	3	3		2						3			

1: Low, 2: Medium, 3: High