ANNA UNIVERSITY: CHENNAI 600 025

NON AUTONOMOUS COLLEGES AFFILIATED TO ANNA UNIVERSITY

REGULATIONS – 2021

M. TECH. PHARMACEUTICAL BIOTECHNOLOGY

CHOICE BASED CREDIT SYSTEM

I TO IV SEMESTERS CURRICULUM AND SYLLABUS

PROGRAM EDUCATIONAL OUTCOMES (PEOs)

PEO1:	To provide our students with a rigorous postgraduate education that will enable them to flourish in research and career in the field of pharmaceutical biotechnology.
PEO2:	To give students a firm foundation in the principles of engineering, science, and statistics required to address issues relating to biologicals and biopharmaceuticals.
PEO3:	To equip the students with the necessary scientific and technological knowledge to understand, evaluate, design and develop original solutions for health-related issues.
PEO4:	To instill in pupils a sense of professional and scientific ethics, scientific communication abilities, and collaboration abilities, a multidisciplinary strategy, and the capacity to address health-related issues on a larger scale social setting.

PROGRAM OUTCOMES (POS)

PO1:	Acquire in-depth knowledge of Pharmaceutical sciences, Biological sciences and Bioengineering for gaining ability to develop innovative solutions and evaluate new ideas for societal benefits.
PO2:	Facilitate the students to gain the wisdom of fundamentals and advances to practice pharmaceutical biotechnology, interdisciplinary research and entrepreneurship as career of constructive service to society and higher learning.
PO3:	Articulate a degree of mastery over the area as per the specialization of the program.
PO4:	Recognize the need for continuous learning and will prepare oneself to create, select, learn and apply appropriate techniques, resources, and modern instrumentation to solve complex biotechnological activities.
PO5:	Possess scientific or technological knowledge in the domain of Pharmaceutical Biotechnology and recognize opportunities to demonstrate a capacity for teamwork, effective communication, decision-making based on open-mindedness and rational analysis in order to achieve common goals.
PO6:	Demonstrate knowledge of Pharmaceutical biotechnology and management principles and apply to manage projects efficiently and economically with intellectual integrity and ethics for sustainable development of society.

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REGULATIONS 2021

M.TECH. PHARMACEUTICAL BIOTECHNOLOGY

CHOICE BASED CREDIT SYSTEM

I TO IV SEMESTERS (FULL TIME) CURRICULA

SEMESTER I

S. No.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.		Analytical techniques in Pharmaceutical Biotechnology	PCC	3	0	0	3	3
2.		Pharmaceutical Microbiology	PCC	3	0	0	3	3
3.		Industrial Fermentation	PCC	3	0	0	3	3
4.		Research Methodology and IPR	RMC	2	0	0	2	2
5.		Drug Regulatory Affairs	PCC	3	0	0	3	3
6.		Professional Elective I	PEC	3	0	0	3	3
7.		Professional Elective II	PEC	3	0	0	3	3
8.		Audit Course*	AC	2	0	0	2	0
PRACTICALS								
9.		Analytical techniques in Pharmaceutical Biotechnology Laboratory	PCC	0	0	6	6	3
			TOTAL	**22**	**0**	**6**	**28**	**23**

*Audit Course is Optional

SEMESTER II

S. No.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.		Protein and Protein Formulations	PCC	3	0	0	3	3
2.		Immunotechnology	PCC	3	0	0	3	3
3.		Techniques in Molecular Biology and Genetic Engineering	PEC	3	0	0	3	3
4.		Professional Elective III	PEC	3	0	0	3	3
5.		Professional Elective IV	PEC	3	0	0	3	3
6.		Open elective	OEC	3	0	0	3	3
7.		Audit Course II*	AC	2	0	0	2	0
PRACTICALS								
8.		Immunotechnology Laboratory	PCC	0	0	6	6	3
9.		Drug discovery Laboratory	PCC	0	0	6	6	3
			TOTAL	**20**	**0**	**12**	**32**	**24**

SEMESTER III

S. No.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
PRACTICALS								
1.		Protein and Protein Formulations Laboratory	PCC	0	0	6	6	3
2.		Bioinformatics and computational biology laboratory	PCC	0	0	6	6	3
3.		Project Work I	EEC	0	0	12	12	6
4.		Summer Internship***	EEC	0	0	0	0	2
			TOTAL	**0**	**0**	**24**	**24**	**14**

SEMESTER IV

S. No.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
PRACTICALS								
1.		Project Work II	EEC	0	0	24	24	12
			TOTAL	**0**	**0**	**24**	**24**	**12**

TOTAL CREDITS: 73

SEMESTER I, ELECTIVES I

S. No.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.		Nanobiotechnology	PEC	3	0	0	3	3
2.		Thermodynamics for Biological Systems	PEC	3	0	0	3	3
3.		Enzyme Engineering and Technology	PEC	3	0	0	3	3
4.		Metabolic Process and Engineering	PEC	3	0	0	3	3

SEMESTER I, ELECTIVES II

S. No.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.		Applied Biopharmaceutics and Pharmacokinetics	PEC	3	0	0	3	3
2.		Molecular Medicine	PEC	3	0	0	3	3
3.		Biogenerics and Biopharmaceuticals	PEC	3	0	0	3	3
4.		Environmental Biotechnology	PEC	3	0	0	3	3

SEMESTER II, ELECTIVES III

S. No.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.		Bioinformatics and Computational Biology	PEC	3	0	0	3	3
2.		Bioprocess Engineering and Technology	PEC	3	0	0	3	3
3.		Molecular Pharmacology	PEC	3	0	0	3	3
4.		Bioconjugate Technology	PEC	3	0	0	3	3

SEMESTER II, ELECTIVES IV

S. No.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.		Pharmacogenomics	PEC	3	0	0	3	3
2.		Bio-entrepreneurship	PEC	3	0	0	3	3
3.		Biomaterials and Tissue Engineering	PEC	3	0	0	3	3
4.		Advances in Omics Sciences and Technology	PEC	3	0	0	3	3

PROFESSIONAL CORE (PCC)

S. NO.	COURSE CODE	COURSE TITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.		Analytical techniques in Pharmaceutical Biotechnology	PCC	3	0	0	3	3
2.		Pharmaceutical Microbiology	PCC	3	0	0	3	3
3.		Industrial Fermentation	PCC	3	0	0	3	3
4.		Drug Regulatory Affairs	PCC	3	0	0	3	3
5.		Protein and Protein Formulations	PCC	3	0	0	3	3
6.		Immunotechnology	PCC	3	0	0	3	3
7.		Analytical techniques in	PCC	0	0	6	3	3

		Pharmaceutical Biotechnology Laboratory						
8.		Immunotechnology Laboratory	PCC	0	6	6	3	3
9.		Drug discovery Laboratory	PCC	0	6	6	3	3
10.		Protein and Protein Formulations Laboratory	PCC	0	6	6	3	3
11.		Bioinformatics and computational biology laboratory	PCC	0	6	6	3	3

PROFESSIONAL ELECTIVE COURSES (PEC)

S. NO.	COURSE CODE	COURSE TITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.		Nanobiotechnology	PEC	3	0	0	3	3
2.		Thermodynamics for Biological Systems	PEC	3	0	0	3	3
3.		Enzyme Engineering and Technology	PEC	3	0	0	3	3
4.		Metabolic Process and Engineering	PEC	3	0	0	3	3
5.		Techniques in Molecular Biology and Genetic Engineering	PEC	3	0	0	3	3
6.		Applied Biopharmaceutics and Pharmacokinetics	PEC	3	0	0	3	3
7.		Molecular Medicine	PEC	3	0	0	3	3
8.		Biogenerics and Biopharmaceuticals	PEC	3	0	0	3	3
9.		Environmental Biotechnology	PEC	3	0	0	3	3
10.		Bioinformatics and Computational Biology	PEC	3	0	0	3	3
11.		Bioprocess Engineering and Technology	PEC	3	0	0	3	3
12.		Molecular Pharmacology	PEC	3	0	0	3	3
13.		Bioconjugate Technology	PEC	3	0	0	3	3
14.		Pharmacogenomics	PEC	3	0	0	3	3
15.		Bio-entrepreneurship	PEC	3	0	0	3	3
16.		Biomaterials and Tissue Engineering	PEC	3	0	0	3	3
17.		Advances in Omics Sciences and Technology	PEC	3	0	0	3	3

EMPLOYABILITY ENHANCEMENT COURSES (EEC)

S. NO.	COURSE CODE	COURSE TITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
PRACTICALS								
1.		Summer internship***	EEC	0	0	0	0	2
2.		Project Work I	EEC	0	0	12	12	6
3.		Project Work II	EEC	0	0	24	24	12

RESEARCH METHODOLOGY AND IPR (RMC)

S. NO.	COURSE CODE	COURSE TITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.		Research Methodology and IPR	PEC	2	0	0	2	2

SUMMARY

S. NO.	Subject Area	CREDITS PER SEMESTER				TOTAL CREDITS
		I	II	III	IV	
1.	RMC	2				2
2.	PCC	15	13	6		37
3.	PEC	6	6			12
4.	OEC		3			3
5.	EEC			8	12	20
	TOTAL	**23**	**24**	**14**	**12**	**73**

ANALYTICAL TECHNIQUES IN PHARMACEUTICAL BIOTECHNOLOGY **L T P C**
3 0 0 3

COURSE OBJECTIVES:

- To enable the students To have a fundamental knowledge about the molecular spectroscopy, NMR and Mass spectroscopy
- To acquire knowledge on different chromatographic methods for separation of pharmaceutical and biotechnological products.
- To acquire knowledge about the principles and operations of various modern analytical instruments.

UNIT I MOLECULAR SPECTROSCOPY **9**

UV-Visible spectroscopy- Theory, Laws, Instrumentation, and applications; IR spectroscopy: Theory, Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer and Applications; Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications, Case studies on applications of molecular spectroscopy.

UNIT II NMR SPECTROSCOPY **9**

Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Principles of 1H-NMR and 13C NMR. Pharmaceutical and biological applications of NMR spectroscopy.

UNIT III MASS SPECTROSCOPY **9**

Principle, Theory, Instrumentation, Types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI, Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Pharmaceutical and biological applications of Mass spectroscopy, Case studies on biological applications of mass spectroscopy.

UNIT IV CHROMATOGRAPHY **9**

Analytical & Preparative concepts of - Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of High-performance Thin Layer chromatography, Ion exchange chromatography, Column, Gas, High Performance Liquid chromatography and Affinity chromatography, Case studies on usage of ion exchange, HPLC and affinity chromatography in industrial applications.

UNIT V ELECTROPHORESIS & IMMUNOASSAYS **9**

Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: Gel electrophoresis, Capillary electrophoresis, Zone electrophoresis, Iso electric focusing; RIA (Radio immuno assay), ELISA and Bioluminescence assays; Analysis of host cell protein (HCP) and host cell DNAs (HCD) in biopharmaceuticals, viable cell analysis, measurement of energy metabolism of live cell, metabolic analyzer – principle and instrumentation.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

On completion of the course, students will able to

1. Understand the fundamental principles and applications of UV-visible, IR, flame emission, atomic absorption, NMR and Mass spectroscopy
2. Demonstrate the principles and applications of chromatographic and electrophoretic separation techniques
3. Recognize the importance of modern instruments in the pharmaceutical analysis
4. Apply the theoretical knowledge of instruments for new analytical method development in screening of various pharmaceutical agents.

5. Develop ability to involve in chemical and biological standardization of pharmaceutical products.
6. Assess appropriate techniques for the analysis of various pharmaceuticals and biotechnological products.

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	1	1	1
CO2	3	3	3	1	1	1
CO3	1	2	3	2	1	
CO4	3	2	3	3	1	
CO5	3	2	3	2	1	
CO6	3	3	3	3		

(1, 2 and 3 are correlation levels with weightings as Slight (Low), Moderate (Medium) and Substantial (High) respectively)

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers. 4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

PHARMACEUTICAL MICROBIOLOGY

L T P C
3 0 0 3

COURSE OBJECTIVES:

Upon successful completion of this course the student will be able to

- Understand the mechanism of action of chemotherapeutic and antibiotic resistence.
- Identify the microorganisms of relevance to healthcare and the pharmaceutical industry and their sources.
- obtain the knowledge on microbial contamination/product spoilage and antimicrobial preservation in pharmaceutical formulations

UNIT I CHEMOTHERAPEUTIC AGENTS 9

Introduction to chemotherapeutic agents: History and development of chemotherapeutic agent, Properties of antimicrobial agents, Types of chemotherapeutic agents – Synthetic, Semisynthetic, Natural. Antibiotics: Types of antibiotics with their mode of action; antibacterial, antifungal, antiviral, antiprotozoal

UNIT II ANTIBIOTIC RESISTANCE AND DEVELOPMENT OF NEW THERAPEUTICS 9

Antibiotic resistance: Development of antibiotic resistance amongst pathogens Mechanism of antibiotic resistance, Disease management methods. Antimicrobial Peptides: History, properties,

sources, mode of action, application. Plant based therapeutic agents. Different prophylactic and therapeutic methods in control of infections. Introduction to virology.

UNIT III CLEAN ROOM TECHNOLOGY AND BIOSAFETY REGULATIONS 9

Microbial contamination spoilage and hazard Sources of contamination, factors affecting survival and growth. Methods of sterilizations: Steam, dry heat, Radiation, Gaseous and Filtration. Clean room technology and its regulatory aspects. Principles of sterilizations with respect to pharmaceutical industries. Biosafety regulations- BSL-1, BSL-2, BSL-3 and BSL-4.

UNIT IV PRESERVATION OF PHARMACEUTICAL PRODUCTS 9

Principles of preservation: objectives of preservation, the ideal preservative, rational development of a product preservative system etc. Antimicrobial preservatives and their properties: antimicrobial activity, factors affecting antimicrobial activity, preservative monographs. Preservative stability and efficacy. Evaluation methods of Preservative and testing.

UNIT V MICROBIAL FERMENTATIONS 9

Industrial importance of microbes in the production of Enzymes - Amylase, Invertase, Proteolytic. Vaccines -Recombinant and Synthetic Vaccines. Organic acids-citric acid, acetic acid, and α- keto glutaric acid. Bio-insecticides-Bacillus sp., Baculovirus. Antibiotics- Penicillin, Bacitracin, Streptomycin. Vitamins-Vitamin B12, Vitamin A, Riboflavin.

SELF STUDY TOPICS (NOT FOR EXAMINATIONS): Role of microbes in the degradation of pollutants / toxic compounds, Microbial waste products in the market.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

CO 1	Describe the structure and types of antimicrobial chemotherapeutic agents and their mode of action
CO 2	apply the knowledge of biochemical and genetic basis for antibiotic resistance and its control mechanism
CO 3	explain the various sterilization techniques and evaluate the sterility testing of pharmaceuticals.
CO 4	earn about various antimicrobial preservatives used in Pharmaceuticals and its evaluation methods
CO 5	ustrate the principle in fermentation process and techniques for antibiotics, enzymes and vitamin production.
CO 6	lentify the microorganisms of relevance to healthcare and the pharmaceutical industry and microbial production and evaluation of pharmaceuticals

CO-PO Mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO 1	3	2			3	1
CO 2	3	2	2		3	
CO 3	3	3		2	3	
CO 4	3	2	2	3	3	
CO 5	3	3	2	3	3	
CO 6	2	3	3	3	3	1

REFERENCES:

1. Hugo, WB and Russell, AD. Pharmaceutical Microbiology, (2003). Blackwell Science, Oxford,

UK.
2. Geoffrey Hanlon and Norman Hodges. Essential Microbiology for pharmacy and pharmaceutical science. (2013).Wiley Blackwell.
3. S. P. Vyas & V. K. Dixit. Pharmaceutical Biotechnology. (2003) CBS Publishers & Distributors, New Delhi.
4. Prescott's Microbiology 8th Edition by Willey, Joanne, Sherwood, Linda, Woolverton, Chris.
5. Davis, B. D., Dulbecco, R, Eisen, H. N., Ginsberg, R. S. Microbiology. (1990). Harper and Row Publishers, Singapore.
6. L.E. Casida, Industrial microbiology, New Age International Publishers.2005

INDUSTRIAL FERMENTATION

L T P C
3 0 0 3

COURSE OBJECTIVES:

- To enable the students to understand the concepts of fermentation technology applied to industrial processes for making products: fermenters, reaction kinetics, media formulation, utilization of microbial cultures, design aspects of bioreactors.

UNIT I INTRODUCTION TO BIOREACTOR DESIGN AND CONSTRUCTION 9

Bioreactor selection criteria and classification, Parameters for control, Design of ideal reactors, Single (Batch, Flow) and multiple reactors, Non-Ideal flow, RTD studies, Modelling of Non-ideal flow reactors, Design and operation of various bioreactors, viz CSTF, fed batch systems, air-lift bioreactors, fluidized bed bioreactors, Scale-up studies.

UNIT II MICROBIAL KINETICS AND DESIGN OF VARIOUS CULTIVATION PROCESSES 9

Immobilized and solid state cultivation; Kinetics of growth in batch continuous and fed batch culture. Specific growth rate, doubling time, growth yield, metabolic quotient; stoichiometry- balance equation, carbon- nitrogen balance, oxidation - reduction principles, product formation. Biomass productivity, comparison with batch cultures, residual time distribution, test of validity; product formation, total cell retention cultivation, . Effect of inhibitors and activators on growth.

UNIT III MODELING OF RECOMBINANT CULTIVATION ANIMAL AND PLANT CELL CULTIVATION SYSTEMS FORTHERAPEUTIC PROTEINS 9

Structured models of metabolism and growth, models of gene expression and regulation, a generalized model of plasmid replication, Genetic instability, predicting host-vector interactions and genetic instability. Process considerations for utilizing genetically engineered strains. Media, aeration in cell culture systems, Bioreactors for plant/animal suspension culture, cell immobilization and organized tissue, bioreactor considerations for animal /plant cell culture for production of pharmaceuticals, Therapeutic proteins and Monoclonal antibodies. Industrial applications of the bioreactors as cell cultivation systems. Introduction to cell banking and storage -.mammalian, insects, stem cells and Microbes.

UNIT IV DOWNSTREAM PROCESSING AND SEPARATION TECHNIQUES 9

Characteristics of biological materials: Recovery and purification of fermentation products; pretreatment methods; Separation of cell mass: centrifugation, clarification and filtration; removal of host cells proteins (HCP) and viral plasmids proteins, viral inactivation. Modern techniques: Electrophoresis; Chromatographic methods; Membrane processes- Ultrafiltration; Reverse osmosis; Cross flow filtration; Microfiltration; Isoelectric focusing; Affinity based separations. Advantages and disadvantages of the above methods.

UNIT V CASE STUDIES IN FERMENTATION DERIVED PRODUCTS 9

Case studies on Whole cell immobilization and their industrial application. Production of penicillin, recombinant Insulin, amino acids-lysine and glutamic acid. Enzymes -amylase and protease. Case studies should deal with strain improvement, medium design, reactor design and process optimization etc.

SELF STUDY TOPICS (NOT FOR EXAMINATIONS): Drying, Drying curve, Batch and continuous dryers, Case studies for the separation of intracellular and extracellular products, Evaporation and crystallization.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

After completion of the course, a student will be able to achieve these outcomes

1. Apply the knowledge of fermentation technology in industrial processes
2. Handle and utilize microbial systems for biological reactions for making products
3. Design and use of reactor systems for bioprocesses.
4. Analyse kinetics of cell and product formation in batch, continuous and fed-batch cultures
5. Differentiate the rheological changes during fermentation process
6. Detail the downstream process of fermentation of important microbial products**.**

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	1			
CO2	2	2	1			
CO3				2		
CO4	1	1		2		
CO5	1	1	1	2		
CO6	1			2		

REFERENCES

1. Stanbury, Stephen. P. F., Hall, J. and Whitaker, A. “Principles of fermentation technology” Elsevier3rd edition.
2. Bailey, J.E. and Ollis, D.F. “Biochemical Engineering Fundamentals” 2nd Edition.,McGrawHill,1986.
3. B.Sivashankar, “Bioseparation principles and techniques”. Prentice Hall of India Pvt Ltd 2007
4 Blanch, H.W and Clark D.S., “Biochemical Engineering”, Marcel Dekker,1997
5. Doran, Pauline M, “Bioprocess Engineering Principles”. Academic Press, 1995
6. Nielsen, J. and Villadsen, J. “Bioreaction Engineering Principles”. Springer, 2007.
7. Shuler, M.L. and Kargi, F. “Bioprocess Engineering: Basic Concepts”. 2nd Edition, Prentice-Hall,2002.

RESEARCH METHODOLOGY AND IPR

L T P C
2 0 0 2

COURSE OBJECTIVES:

- To impart knowledge and skills required for research and IPR:
- Problem formulation and use of various research designs
- Know different means of data collection
- How to analyze and interest as well as present data in different modes like Technical paper writing / presentation without violating professional ethics
- Patent drafting and filing patents

UNIT I RESEARCH DESIGN **6**

Overview of research process and design, Use of Secondary and exploratory data to answer the Research question, Qualitative research, Observation studies, Experiments and Surveys.

UNIT II DATA COLLECTION AND SOURCES **6**

Measurements, Measurement Scales, Questionnaires and Instruments, Sampling and methods. Data - Preparing, Exploring, examining and displaying.

UNIT III DATA ANALYSIS AND REPORTING **6**

Overview of Multivariate analysis, Hypotheses testing and Measures of Association. Presenting Insights and findings using written reports and oral presentation.

UNIT IV INTELLECTUAL PROPERTY RIGHTS **6**

Intellectual Property – The concept of IPR, Evolution and development of concept of IPR, IPR development process, Trade secrets, utility Models, IPR & Bio diversity, Role of WIPO and WTO in IPR establishments, Right of Property, Common rules of IPR practices, Types and Features of IPR Agreement, Trademark, Functions of UNESCO in IPR maintenance.

UNIT V PATENTS **6**

Patents –objectives and benefits of patent, Concept, features of patent, Inventive step, Specification, Types of patent application, process E-filling, Examination of patent, Grant of patent, Revocation, Equitable Assignments, Licences, Licensing of related patents, patent agents, Registration of patent agents, Indian Patents and Designs, Act 1911.

SELF STUDY TOPICS (NOT FOR EXAMINATIONS): Attending WIPO free courses, criteria for patentability.

TOTAL:30 PERIODS

COURSE OUTCOMES:

After completion of the course the students will be able to

CO1:	Identify and formulate the research problems.
CO2:	Collect the data related to research problem from different sources.
CO3:	Analysis the data related to research problem.
CO4:	Understand and role and responsibilities of different organization in the protection of intellectual property rights.
CO5:	Describe about patents and procedure for obtaining patents.
CO6:	Understand the interrelationships between research problems and the process procedure in filling patents in Research and Development.

CO – PO MAPPING						
RESEARCH METHODOLOGYAND IPR						
CO	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3			2		2

CO2	3				2	2
CO3	3				1	2
CO4	3		2		1	2
CO5	3	3	2	2	1	2
CO6	3		2		2	2

REFERENCES:

1. Cooper Donald R, Schindler Pamela S and Sharma JK, "Business Research Methods", Tata McGraw Hill Education, 11e (2012).
2. Catherine J. Holland, "Intellectual property: Patents, Trademarks, Copyrights, Trade Secrets", Entrepreneur Press, 2007
3. David Hunt, Long Nguyen, Matthew Rodgers, "Patent searching: tools & techniques", Wiley, 2007.
4. S. Lakshmana Prabu, TNK. Suriyaprakash, Eduardo Jacob-Lopes, Leila Queiroz Zepka, "Intellectual Property Rights – Patent", InTech, Croatia, 2020.
5. The Institute of Company Secretaries of India, Statutory body under an Act of parliament, "Professional Programme Intellectual Property Rights, Law and practice", September 2013.

DRUG REGULATORY AFFAIRS **L T P C**
3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Enable the students to learn about the drug regulatory laws and the agencies in India and at International level.
- Acquire knowledge of quality drug standards and drug development approval processes
- Attain the knowledge of product safety management.

UNIT I INTRODUCTION TO DRUG REGULATORY LAWS 9

History, Organization and functions of USFDA, EMEA, Australia TGA, U.K. MHRA, WHO, ICH and ISO. Indian drug regulatory authorities, Central and State regulatory bodies. Need for pharmaceutical regulations**-** Drugs and Cosmetics Act and Rules 1940 with latest Amendments, Special emphasis – Schedule M and Y. The Drugs (Price Control) Order 2013 with its amendments, The drugs and Magic Remedies (Objectionable advertisements) Act 1954, Guidelines for evaluation of nanopharmaceuticals in India.

UNIT II PHARMACOPOEIA 6

Purpose of Pharmacopoeias- Descriptions & Monographs; Standards and Specifications; Testing of Drugs; Various Countries Pharmacopoeias; Indian, British, U.S, European, Japanese and International pharmacopoeia.

UNIT III cGMPs& REGULATORY RECORDS 10

cGMP concepts — Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs. Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN). Drug dossier contents - CTD (CMC section) & data. cGMP& ICH guidelines for Accelerated stability Testing.

UNIT IV DRUG DEVELOPMENT APPROVAL PROCESS/CLINICAL TRIALS 10

Drug development stages, FDA guidelines on IND, NDA, ANDA approvals. European regulatory agency: types of filing process (Centralized, decentralized, RMS countries), Regulation of preclinical studies, Schedule-Y, Introduction to animal ethics; Animal rights and use of animals in the advancement of medical technology; Introduction to laws and regulations regarding the use of animals in research. Good Clinical Practice (ICHGCP) guidelines, History and Idea behind GLP, Areas of Application of GLP, GMP compliance audit

UNIT V QUALITY MANAGEMENT SYSTEMS 10

Introduction to GDP, data management and integrity, Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)] and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

TOTAL:45 PERIODS

COURSE OUTCOMES:

At the end of the course the students will be able to,

1. Apply the knowledge of drug regulatory laws.
2. Acquire the knowledge of pharmacopoeia standards.
3. Know the quality guidelines and the drug regulating authorities in different countries.
4. Have an insight about drug regulatory approval process and clinical trials in pharmaceutical industry.
5. Assure the learning of product safety management concepts in pharmaceutical industry.
6. Acquire the knowledge of drug regulatory, quality and safety management in pharmaceutical industry

CO– PO mapping

Course outcome		Programme Outcomes (PO)					
		1	2	3	4	5	6
CO 1	Apply the knowledge of drug regulatory laws.	1		1			2
CO 2	Acquire the knowledge of pharmacopoeia standards	1					1
CO 3	Know the quality guidelines and the drug regulating authorities in different countries	1					
CO 4	Have an insight about drug regulatory approval process and clinical trials in pharmaceutical industry.	2	1	1		2	3
CO 5	Assure the learning of product safety management concepts in pharmaceutical industry.	2					3
CO 6	Acquire the knowledge of drug regulatory, quality and safety management in pharmaceutical industry	2	1	1		1	2

REFERENCES:

1. N Udupa and Krishnamurthy Bhat. A Concise Textbook of Drug Regulatory Affairs , ManipalUniversity Press, Edition: 1, 2015.
2. David M.Bleisner, Establishing a cGMP Laboratory Audit System, A practical Guide, Wiley Publication, 2006.
3. Abraham, John and Smith, H.W. “Regulation of the Pharmaceutical Industry”, Palgrave, Macmillan,2003.

4. Weinberg, Sandy "Good Laboratory Practice Regulations" 4th Edition,Marcel Dekker,2007.
5. Gad, Shayne C. "Drug Safety Evaluation", Wiley-Interscience, 3rd Edition, 2016.
6. Good Clinical, Laboratory and Manufacturing Practices Techniques for the QA Professional, Edited by PA Carson,and N Dent,, The Royal Society of Chemistry 2007, Published by The Royal Society of Chemistry, Thomas Graham House, Science Park, Milton Road, Cambridge CB4 0WF, UK
7. Laboratory Auditing for Quality and Regulatory compliance bu Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150. 2005.
8. Berry, Ira R. and Harpaz, Daniel "Validation of Active Pharmaceutical Ingredients",2ndEdition, CRC Press, 2001
9. British Pharmacopoeia, Andesite Press, 2021.
10. United States Pharmacopoeia, 2020
11. https://cdsco.gov.in/opencms/opencms/en/Home/
12. https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations

ANALYTICAL TECHNIQUES IN PHARMACEUTICAL BIOTECHNOLOGY LABORATORY

L	T	P	C
0	0	6	3

COURSE OBJECTIVES:

- carry out analytical experiments related to spectroscopic and chromatographic techniques.
- enable students to learn the principles of analysis for pharmaceutical and biotechnological applications
- provide students of various analytical skills, in relevance of pharmaceutical dosage forms and analytical instrumentation,

LIST OF EXPERIMENTS

1. UV/Visible Spectroscopy
   i) Calibration of UV spectrophotometer
   ii) Effect of solvent on wavelength maxima of drugs.
   iii) Validation of Beers lambert laws.
   iv) Standard calibration curve by UV spectroscopy at λ max, λ max + 10 nm and λ max – 10 nm
   v) Determination of pKa by U.V. spectroscopy.
   vi) Multicomponent analysis by UV-Spectrophotometry by different methods
   vii) Analysis of drugs from formulations focusing on separation of drug from the formulation excipients.
2. Fluorescence spectroscopy:
   i) Excitation and emission spectra for the fluorescent dye fluorescein.
   ii) Effect of concentration and instrumental bandwidth on the fluorescent signal.
3. IR Spectroscopy
   i) Calibration of IR spectrophotometer
   ii) Sample preparation for I.R. spectroscopy (solid/liquids) and interpretation of IR bands for important functional groups.
4. Chromatography:
   i) HPLC calibration of HPLC column and determination of response factor by HPLC
   ii) Separation of components by HPTLC and column chromatography.
5. Structural Interpretation by Spectroscopy:

i) Basic interpretations of simple Mass spectra and NMR.

ii) Structural elucidation workshop: Interpretation of 1H NMR, 13C NMR, IR and Mass spectrometry of simple compounds.

TOTAL: 90 PERIODS

COURSE OUTCOMES:

At the end of the course, the student able to

1. Operate spectroscopic and chromatographic instruments.
2. Assess sources of error in instrumental analysis and perform calibration of instruments.
3. Conduct the chromatographic separation and spectroscopic analysis of drugs.
4. Interpret the structure of the organic compounds with the given spectral data.
5. Develop ability to involve in qualitative and quantitative analysis of drugs and biologics.
6. Appreciate the importance of modern instruments in the quality control and research

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3		
CO2	3	2	3	2	2	
CO3	3	3	3	3		
CO4	3	3	3	3		
CO5	3	3	3	3		
CO6	3	3	3	3	2	

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Loyd V. Allen Jr, “Remington: The Science and Practice of Pharmacy”. Vol. I & II, 22nd Edition, Pharmaceutical Press;, 2012.
3. Kenneth A. Connors, “Textbook of Pharmaceutical Analysis”, 3rd Edition, John wiley and sons, New York, 2007.
4. Siddiqui, Anees A, “Pharmaceutical Analysis”. Vol.I & II, 3rd edition, CBS Publishers, 2014.
5. Takeru Higuchi, Einar Brochmann, Hanffen Hanssen, Hamffen Hanssen, “Pharmaceutical Analysis” 1st Edition, CBS Publishers, 2005.

SEMESTER II

PROTEIN AND PROTEIN FORMULATIONS **L T P C**

3 0 0 3

COURSE OBJECTIVES:

- To provide the basic concepts of protein and protein formulations.
- To instill the principles of protein formulation and design
- To impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations

UNIT I PROTEIN ENGINEERING **9**

Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability.

UNIT II PEPTIDOMIMETICS 9

Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design.

UNIT III PROTEOMICS 9

Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags. 2-Dimensional gel electrophoresis Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments. Purpose of Protein glycosylation- effect of protein glycosylation on the proteome

UNIT IV PROTEIN FORMULATION 9

Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in preformulation, Liposomes, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

UNIT V METHODS OF PROTEIN SEQUENCING 9

Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

TOTAL: 45 PERIODS

COURSE OUTCOMES

At the end of the course the students will be able to

1. Understand the fundamentals of protein engineering.
2. Discuss the underlying concepts of peptidomimetics and drug design.
3. Demonstrate the characterization techniques for protein molecules.
4. Incorporate approaches to formulate stable protein formulation.
5. Elicit concepts of the protein sequencing.
6. Become expertise in the technology of Protein and Protein Formulations

CO – PO mapping

Course Outcome	Programme Outcomes (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	2	2	1	1		
CO2	2	2			1	
CO3	1	1		2	2	
CO4		2	2	2	2	1
CO5	2	2	1			
CO6			2	2	1	1

REFERENCES:

1. Eugene J. McNally, Jayne E. Hastedt Protein Formulation and Delivery, Informa Healthcare USA, Inc 2008
2. Engelbert Buxbaum, Fundamentals of Protein Structure and Function, Springer International Publishing Switzerland 2015
3. Ajay K. Banga Therapeutic Peptides and Proteins Formulation, Processing, and Delivery Systems. 3rd Edition, 2015. CRC Press, Taylor & Francis USA.

4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, 1ST Edition, 2009, CRC press. USA
5. Jeffrey L. Cleland, Rober Langer. Formulation and Delivery of Proteins and Peptides. ACS, USA.
6. Robert K. Skopes. Protein purification, principles and practice, springer, New york.
7. David Whitford, Proteins-Structure and Function, 1st Edition, 2005. John Wiley & Sons, USA.
8. Lars Hovgaard, Sven Frokjaer, Marco van de Weert. Pharmaceutical Formulation Development of Peptides and Proteins. 2nd Edition, CRC Press, Taylor & Francis, USA.

IMMUNOTECHNOLOGY

L	T	P	C
3	0	0	3

COURSE OBJECTIVES:

The course aims to

- understand the applications of immunology for the development of diagnostics
- understand the basic principles of vaccine development
- make use of the knowledge of immunotechnology for clinical applications and also become aware of the regulatory issues.

UNIT I INTRODUCTION **6**

Review on Cells of the immune system and their development; primary and secondary lymphoid organs; humoral immune response; cell mediated immune responses; complement, classification of T cells and B cells, cell markers.

UNIT II ANTIBODIES **11**

Development of Monoclonal antibodies, classification and their applications; ELISA – types; IFT (direct and indirect) Agglutination tests; Antigen detection assay; Plaque Forming Cell Assay, Development of rapid immunodiagnostics - Immuno- lateral flow / flow through assays. Diagnosis of immediate and delayed hypersensitivity, anaphylactic reaction, total Ig and antigen specific IgE antibody assay, assay for hemolytic diseases, assay for immune complex, skin tests for DTH response

UNIT III DEVELOPMENT OF IMMUNOASSAYS **10**

PBMC separation from the blood; identification of lymphocytes based on CD markers; FACS; Lympho proliferation assay; Mixed lymphocyte reaction; Cr51 release assay; macrophage cultures; cytokine bioassays- IL2, gamma IFN, TNF alpha.; HLA typing.

UNIT IV VACCINE TECHNOLOGY **10**

Principles of vaccine development, types; Development of vaccines for bacterial, viral and parasitic diseases, Regulatory requirements for vaccine development and testing, ethical issues, protein based vaccines; sub-unit vaccines, DNA vaccines; Plant based vaccines; recombinant antigens as vaccines; reverse vaccinology, cancer vaccines, customized therapeutic cancer vaccines, (scFv) antibodies and molecular evolution of scFv for enhanced sensitivity and specificity,

UNIT V DEVELOPMENT OF IMMUNOTHERAPEUTICS **8**

Development of effective immuno drug targets for infectious diseases, engineered antibodies; catalytic antibodies; idiotypic antibodies; dendritic cells based immunotherapy, combinatorial libraries for antibody isolation, CAR T-cell therapy, Immune check point inhibitors.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of the course the students will be able to

1. understand the science of immunotechnology
2. comprehend the concepts of antibodies and its characterization
3. describe the developments in the immunoassays
4. gain the knowledge of vaccine development
5. apply the technology for the development of immunotherapeutics and Diagnosis
6. become an entrepreneur in the field of immunotechnology

CO – PO mapping

Course Outcomes	Programme Outcomes (PO)					
	1	2	3	4	5	6
CO1	3	2	1			
CO2	2	2	1			
CO3				2	2	
CO4	1	1		2	2	
CO5	1	1	1	2	2	
CO6				2	2	2

REFERENCES:

1. Roitt, Ivan. Essential Immunology 9th Edition., Blackwell Scientific, 13th edition, 2017
2. Roitt I., Brostoff J. and Male D. Immunology, 6th ed. Mosby, 2001
3. Goldsby , R.A., Kindt, T.J., Osbome, B.A. and Kerby J. Immunology, 6th ed., W.H.Freeman, 2006
4. Janeway's Immunobiology, Ninth Edition, Kenneth M. Murphy, Casey Weaver, 2017
5. Roitt's Essential Immunology, 13th Edition, Peter J. Delves, Seamus J. Martin, Dennis R.Burton, Ivan M. Roitt, 2017
6. Lippincott Illustrated Reviews: Immunology, 2nd ed., 2012

TECHNIQUES IN MOLECULAR BIOLOGY AND GENETIC ENGINEERING

L T P C
3 1 0 4

COURSE OBJECTIVES:

- This course is aimed to teach students with different approaches to perform molecular biology, genetic engineering, rDNA technology and their practical applications in biotechnological research as well as in pharmaceutical industries.

UNIT I VECTOR SYSTEMS 12

Overview of tools in recombinant DNA technology. Artificial chromosomes — YACs and BACs. Principles for maximizing gene expression — expression vectors, pMal, GST, pET-based vectors. Protein purification — His-tag, GST-tag and MBP-tag. Intein-based vectors; Inclusion bodies; methodologies to reduce formation of inclusion bodies; mammalian expression and replicating vectors; Baculovirus and Pichia vectors system, plant based vectors, Ti and Ri plasmids as vectors,yeast vectors and shuttle vectors.

UNIT II ASSAY TECHNIQUES IN MOLECULAR BIOLOGY 12

Nuclease protection assays, Nuclease S1 mapping, Reporter assays — Mono and dual reporter assays, Electrophoretic mobility shift assay (EMSA) / Gel shift assay, Run-off transcription assay,

Phage display, Ribosome display, Gene silencing – siRNAs and Morpholinos.

UNIT III HIGH-THROUGHPUT DNA SEQUENCING 12

Preparation of Next Generation Sequencing (NGS) libraries: Fragmentation versus tagmentation, end repair, clonal amplification — Bridge PCR and emulsion PCR. Basics and steps involved in NGS platforms: Illumina/Solexa, Roche 454, Ion-torrent and Pacific biosciences. Current status of Oxford nanopore sequencing. Principles of Mate pair sequencing, ChIP-seq, RIP/CLIP-Seq, Methyl seq —Restriction enzyme, enrichment and bisulfite treatment strategies.

UNIT IV GENE EXPRESSION ANALYSIS 12

Overview of gene expression and its significance. Hybridization methods: Southern and Northern. PCR methods: Reverse transcriptase PCR, End point Vs Real time PCR, Relative quantitation, Absolute quantification — Standard curve method and digital PCR. Endogenous/loading controls. High throughput analysis: Multiplex PCR, Microarray, Serial analysis of gene expression (SAGE) and Small Amplified RNA-SAGE (SAR-SAGE), Total analysis of gene expression (TOGA), Gene calling, RNA-seq and Ribosome profiling.

UNIT V GENOME EDITING TECHNOLOGIES 12

Basics and applications of genome editing methods - Zinc-finger nuclease (ZFN), Transcription activator-like effector nucleases (TALEN), Mega nucleases, CRISPR-Cas systems — Types and applications, Homing endonucleases, Transposons and Cre/lox P systems. Gene delivery systems – Physicochemical methods and viral vectors.

TOTAL: 60 PERIODS

COURSE OUTCOMES:

By the end of the course, the student should be able to

1. detail the basic steps of gene cloning and the role of enzymes and vectors responsible for gene manipulation, transformation and genetic engineering.
2. apply concept of genetic engineering techniques in basic and applied experimental biology.
3. possess proficiency in designing and conducting experiments involving genetic manipulation.
4. demonstrate the skills on gene manipulation, gene expression, etc which prepares them for further studies in the area of genetic engineering.
5. illustrate technical know-how on versatile techniques in recombinant DNA technology.
6. describe the genome editing and sequencing and methods for gene therapy..

. **CO – PO mapping**

Course Outcome	Programme Outcomes (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	3	2	1			
CO2	2	2	1			
CO3				2	2	
CO4	1	1		2	2	
CO5	1	1	1	2	2	
CO6				2	2	

REFERENCES:

1. Steven R. Head, Phillip Ordoukhanian, Daniel R. Salomon. “Next Generation Sequencing:Methods and protocols” 1st Edition, Humana Press, 2018.
2. Krishnarao Appasani. “Genome Editing and Engineering” Cambridge University press 2018.

3. Raghavachari Nalini, Garcia-Reyero Natàlia. “Gene expression analysis: Methods andprotocols” 1st Edition, Humana Press, 2018.
4. Primrose SB and Twyman RB. “Principles of Gene manipulation and Genomics”. 7th Edition,Wiley-Blackwell, 2006.
5. Green MR and Sambrook J. “Molecular Cloning: A Laboratory Manual”. 4th Edition, CSHLpress, 2012.

IMMUNOTECHNOLOGY LABORATORY **L T P C**
0 0 6 3

COURSE OBJECTIVES

The course aims to,

- provide hands-on-experience on handling animal for research and various relevantI immunological techniques like ELISA, Flow cytometry etc.
- provide practical experience on performing and understanding immunoassays forevaluating drugs.
- to obtain laboratory training for different Immunotechnological techniques.

LIST OF EXPERIMENTS

1.*Preparation of antigen and Routes of immunization (Intraperitoneal, Sub-cutaneous, Intramuscular, Intra- nasal, Oral – VIRTUAL DEMO)
2. *Methods of bleeding (Tail bleeding, Intravenous, intraorbital - VIRTUAL DEMO)
3. Collection of serum, storage and purification of total IgG (salt precipitation).
4. Evaluation of Antibody titre by direct ELISA
5. Evaluation of Antigen by Sandwich ELISA
6. Characterization of antigens by native and SDS-PAGE
7. Characterizations of antigens by Western blot analysis – Wet and semi dry transfer
8. Conjugation of Immunoglobins (Streptavidin, colloidal gold)
9. Methods for prototype development of Immunodiagnostics (ICT card)
10. Blood smear identification of leucocytes by Giemsa stain 16
11. Separation of mononuclear cells by Ficoll-Hypaque
12. Separation of splenocytes and proliferation against mitogens
13. Primer design using softwares.
14. Gene DNA amplification by random / specific primers.
15. Western Blotting
16. Gene amplification by PCR.

TOTAL: 90 PERIODS

LIST OF EQUIPMENTS REQUIRED

Microscopes
Purification columns
Microplate reader
UV spectrometer
PAGE apparatus
Western blot apparatus
Centrifuge
Haemocytometer
Cell counter
Metabolic analyser
PCR

COURSE OUTCOMES

At the end of the course, learners will be able to

CO 1	Demonstrate the immunization methods and handling of animals
CO 2	Carry out the experiment on immunological assays for identifying drugs and vaccines.
CO 3	Describe the principles of PCR and their uses in genetic engineering.
CO 4	Illustrate the principle, detection and quantification of protein by bioanalytical techniques
CO 5	Learn about the gene amplification and methods for analysis of DNA
CO 6	Apply methods adapted in gene synthesis

CO-PO Mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO 1	2	2		3		3
CO 2		3	2	3	3	
CO 3		3		3	3	
CO 4	3	3	2	3	3	
CO 5		3	2	3	3	2
CO 6	2		3			2

REFERENCES:

1. "Antibodies", Cold Spring Harbour Laboratory, 1988.
2. Goldsby, R.A. et al."Kuby Immunology". 6th Edition, W.H. Freeman, 2002.
3. Turgeon, Mary Louise. "Immunology and Serology in Laboratory Medicine", 2nd Edition, Elsevier, 2007.
4. Brostoff J et al., "Clinical Immunology", 6th Edition, Gower Medical Publishing, 2002.
5. Coligan, J. E. et al, "Current Protocols in Immunology", 4th Edition John Wiley & Sons, 1994.
6. Paul, "Fundamental of Immunology", 4th Edition, Lippincott Raven, 1999.

DRUG DISCOVERY LABORATORY

L T P C
0 0 6 3

COURSE OBJECTIVES:

This course will explore the process of drug discovery from Synthetic and natural products .

SYNTHETIC METHODS FOR DRUG DISCOVERY

1. Synthesis of selected drugs involving two or more steps of synthesis and study of spectral analysis
   of drug synthesized (Paracetamol, Aspirin, Fluorscein, acetanilide, etc.).
2. Determination of pharmacopoeia standards for the synthesized drugs.

DISCOVERY OF DRUGS FROM NATURAL PRODUCTS

1. Extraction Techniques: Cold maceration, Hot Percolation and Soxhalation.
2. Evaluation of extraction Efficiency by yield calculation and TLC.
3. Isolation and purification of some of the following natural products
   a. Piperine from black pepper
   b. Strychnine and Brucine from *Strychnos nuxvomica* seeds
   c. Caffeine from Tea Powder
   d. Curcumin from Turmeric
   e. Diosgenin from Diascoria tubers
   f. Sennosides from Senna leaves
   g. Embelin from *Emblica ribes* fruits
4. Identification of alkaloids in mixture by TLC.
5. Identification of phytoconstituents like alkaloids, steroids, flavanoids etc in plant extracts by TLC.
6. Separation (of sugars/amino acids) by paper chromatography.
7. Separation of compounds by HPLC
8. Analysis of recorded spectra of some simple organic compounds.
9. Tests to detect alkaloids, steroids, flavanoids and their glycosides.
10. Evaluation of antioxidant potential of herbal extracts using DPPH free Radical scavenging assay.

TOTAL: 90 PERIODS

Required Equipments:

Soxhlet apparatus, rotary flash evaporator, Hot air oven, sonicator, mortar and pestle, TLC chamber, Fume hood, purification columns, micro-plate reader, UV spectrometer, centrifuge, required strains & consumables.

COURSE OUTCOMES:

On completion of this course students should be able to

1. describe the process of drug discovery and development.
2. discuss the challenges faced in each step of the drug discovery process .
3. have gained a basic knowledge of synthetic and extraction methods used in drug discovery.
4. organise information into a clear report.
5. demonstrate their ability to work in teams and communicate scientific information effectively.
6. perform common extraction techniques including maceration, percolation, soxalation etc.

CO-PO Mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO 1	2	2		2		

CO 2	3	1	2	2	2	
CO 3	3	1		2	2	
CO 4	3	3	2	3	3	
CO 5		3	2	3	2	
CO 6	2		3			

REFERENCES

1. Foye's Principles of Medicinal Chemistry. By David A. Williams, Thomas L.Lemke, Thomas L. Lernke, William O. Foye. Lippincott Williams& Wilkins Publishers; 7th Edition,2012.
2. Modern Methods of Plant Analysis – Peech and M. V. Tracey, 1955.
3. Natural Product Chemistry "A laboratory guide" by Raphealikan,2nd edition, 1991.
4. Phytochemistryvol I & II by Miller, Jan, Nostrant, Rein Hid, 2003.
5. Recent advances in Phytochemistry Vol. I & IV – Scilicet, Runeckles.
6. Remington: The Science and Practice of Pharmacy, 21st Edition, 2011.
7. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry. ByJaime N. Delgado (Editor), Ole Gisvold (Editor), William A. Remers (Editor). Lippincott Williams& Wilkins Publishers; 10thEdition (August 1998) ISBN: 0397515839.1998

SEMESTER III

PROTEIN AND PROTEIN FORMULATIONS LABORATORY **L T P C**
0 0 6 3

COURSE OBJECTIVES

The course aims to

- Impart the knowledge of the formulation concepts on proteins.
- Evaluate the various protein and protein formulations through various characterization techniques.
- Expertise in various formulation approaches of proteins.

LIST OF EXPERIMENTS

- Preformulation study with suitable proteins and peptides
- Study on factors influencing solubility profile and partition coefficient of proteins.
- Compatibility and interactions studies of peptides and proteins with pharmaceutical excipients
- Stability study of protein and protein formulations
- Protein estimation using various methods.
- Isolation and estimation of DNA
- Isolation and estimation of RNA
- Estimation of Enzymatic activity.
- Prepare and characterize protein immobilized alginate beads.
- Quality control experiments with marketed protein and protein formulations
- Formulation and characterisation of vesicle based protein and peptide.
- Computational approaches in study of aggregation

LIST OF EQUIPMENTS REQUIRED

- UV Spectrophotometer
- pH Meter
- Analytical Weighing Balance
- Microscopes
- Stability Chamber
- Software for computational works to characterize the protein and protein formulations

TOTAL: 90 PERIODS

COURSE OUTCOMES:

On completion of the course, the student will be able to

1. Execute preformulation study on protein formulations.
2. Carryout the stability protocol on proteins.
3. Isolate and estimate DNA and RNA.
4. Formulate the various protein formulations.
5. Analyse the various quality control test on marketed formulations.
6. Become Expertise in the field of protein formulation discipline

CO – PO mapping

Course Outcome	Programme Outcomes (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	3	1	1		1	1
CO2	2	2	1		1	1
CO3	2	1	1			
CO4	3	2	2	2	2	
CO5	2	2	1	2		2
CO6	2	2		2		2

BIOINFORMATICS AND COMPUTATIONAL BIOLOGY LABORATORY **L T P C**
0 0 6 3

COURSE OBJECTIVES:

The course aims to,

- introduce biopharma related databases, 3D structures of drugs, small molecules and targets
- get familiarized with Next Generation Sequencing Data analysis in a disease context
- perform Quantitative Structure Activity Relationship, Molecular Docking and simulations

LIST OF EXPERIMENTS

1. Introduction to Multiuser Operating System Linux.
2. Databases : Biological and Pharma related.
3. Computing molecular properties of drugs / compounds.
4. Molecular modeling of small molecules : obtaining 3D structures, understanding data formats.
5. Drug targets, Data resources and PDB structures.
6. Homology modeling of Protein Targets and Model evaluation.
7. Next Generation Sequencing Data Analysis Bioconductor Package for Differential gene expression analysis using a disease related dataset.
8. Quantitative Structure Activity relationship (QSAR) Model (partition co-efficient, dissociation constant, molar refractivity, etc.)
9. Pharmacophore identification.
10. Drug like property evaluation of compounds and ADME (Lipinski's rule of five).
11. Methodology of building and refining protein drug targets structure models from X-ray crystallographic data using CCP4i.
12. Molecular docking : Protein – Protein, Protein-Small Molecule.
13. Molecular Dynamics Simulation using GROMACS.
14. Pharmacogenomics : Effect of SNPs / mutations on drug binding using docking approaches.

TOTAL : 90 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

1. Classify different types of Biological Databases.
2. retrieve data related to small molecules, drugs and their targets, use computational tools for their analysis.
3. explain about biological macromolecular structures and structure prediction methods
4. perform basic next generation sequencing data analysis.
5. perform computational structural studies like QSAR, Molecular docking, Molecular Dynamics simulations and interpret the results.
6. Present and discuss experimental results

REFERENCES:

1. Introduction to Bioinformatics by Arthur K. Lesk, Oxford University Press.2014
2. Algorithms on Strings, Trees and Sequences by Dan Gusfield, Cambridge University Press.2004
3. Biological Sequence Analysis Probabilistic Models of proteins and nucleic acids by R.Durbin, S.Eddy, A.Krogh, G.Mitchison, Cambridge University Press,1998
4. Bioinformatics Sequence and Genome Analysis by David W. Mount, Cold Spring Harbor Laboratory Press. 2004
5. Bioinformatics The Machine Learning Approach by Pierre Baldi and SorenBrunak, Cambridge University Press,2001
6. RNA-seq Data Analysis: A Practical Approach, by Eija Korpelainen, Jarno Tuimala, Panu Somervuo, Mikael Huss and GarryWong. CRC Press 2014
7. Next Generation Sequencing Data Analysis, by XinkunWang CRC Press.2016

PROJECT WORK I

L T P C
0 0 12 6

COURSE OBJECTIVES:

The course aims to enable the students to

- identify the problem/process relevant to their field of interest that can be carried out
- search databases and journals to collect and analyze relevant data
- plan, learn and perform experiments to find the solution
- prepare project report

TOTAL : 180 PERIODS

COURSE OUTCOMES:

At the end of the course the students will be able to

1. Identify the research/industrial problems
2. Collect the relevant literature
3. Analyze the relevant literature
4. Design the experiment
5. Conduct experiment and analyse the data
6. Prepare project report

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	2	1	2	1	2	1
CO2	2	1	2	1		1
CO3	2	1	2	1		
CO4	2	1	2	1		1
CO5	2	1	2	1	2	1
CO6		1	2			1

SUMMER INTERNSHIP

L T P C
0 0 0 2

COURSE OBJECTIVES:

1. To strengthen the association of students with Pharma/Biotech Industry.
2. To create awareness amongst the students the recent trends in Pharma/Biotech industries.
3. To percept the role and responsibility of pharmaceutical biotechnologists in Pharma/Biotech industries.

COURSE OUTCOMES:

After completion of the internship students will be able to:

1. learn the application of knowledge in real world problems.
2. expose to team-work and leadership quality.
3. deal with industry-professionals
4. familiarize with ethical issues in the work environment.
5. get self-motivation in learning the courses
6. identify the gap between the professional world and the academic institutions.

CO Vs PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	1	1	1	2		
CO2					2	
CO3				3		
CO4						1
CO5				1	3	2
CO6			1			2

SEMESTER IV

PROJECT WORK II **L T P C**

0 0 24 12

COURSE OBJECTIVES:

The course aims to

- Train students to analyze the problem/ think innovatively to develop new methods/product /process
- Make them understand how to find solutions/ create products economically and in an environmentally sustainable way
- Enable them to acquire technical and experimental skills to conduct experiment, analyze the results and prepare project report
- Enable them to effectively think about strategies to commercialize the product.

TOTAL : 360 PERIODS

.**COURSE OUTCOMES:**

At the end of the project the student will be able to

1. Formulate and analyze problems for developing new methods/solutions/processes.
2. Plan experiments to find solutions in a logical manner
3. Conduct experiments to find solutions in a logical manner
4. Analyze and interpret the results
5. Prepare project report
6. Know the strategies for Commercialization

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	3	2	3	2
CO2	3	2	3			2
CO3	3	2	3	2	3	2
CO4	3	2	3	2		
CO5				2		2
CO6						2

SEMESTER I

ELECTIVE I

APPLIED STATISTICS FOR BIOTECHNOLOGISTS **L T P C**
3 0 0 3

COURSE OBJECTIVES:

This course will help the students to

- Study the mathematical aspects of probability, determination of probability and moments.
- Study the distributions of discrete and continuous random variables and their properties.
- Obtain the covariance and correlation between jointly distributed random variables, interpret simple linear regression and fitting of curves by least square method.
- Study concepts and methods of sampling and various statistical tests in testing hypothesis ondata.
- Analyze one-way, two-way and three-way classifications of analysis of variance and problems using them.

UNIT I PROBABILITY AND RANDOM VARIABLES 9

Sample spaces - Events - Axiomatic approach to probability - Conditional probability - Additional theorem - Multiplication theorem - Baye's theorem — Random variables : Continuous and discrete random variables - Distribution function - Expectation with properties - Moments, mean, variance problems - Continuous and discrete distributions.

UNIT II STANDARD DISTRIBUTIONS 9

Bivariate distribution - Conditional and marginal distribution - Discrete distributions - Binomial, Poisson, Geometric distributions - Continuous distributions - Normal, Exponential and Negative exponential, Gamma distributions - Simple problems - Properties.

UNIT III CORRELATION AND REGRESSION 9

Correlation coefficient - Properties - Problems - Rank correlation - Regression equations - Problems - Curve fitting by the method of least squares - Fitting curves of the form $ax+b$, ax^2+bx+c , ab^x and ax^b - Bivariate correlation application to biological problems.

UNIT IV SAMPLING AND TESTING OF HYPOTHESIS 9

Concept of sampling - Methods of sampling - Sampling distributions and standard error - Small samples and large samples - Test of hypothesis - Type I & Type II Errors - Critical region - Large sample tests for proportion, mean - Exact test based on normal , t , F and Chi - square distribution problems - Test of goodness of fit.

UNIT V ANALYSIS OF VARIANCE 9

Basic principles of experimentation - Analysis of variance - One - way, Two - way classifications - Randomized block design - Latin square design - Problems.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

CO1	illustrate Mathematical basis and foundations of probability and statistics, computation of probabilityand moments, standard distributions of discrete and continuous random variables and standard distributions and their properties

CO2	compute the covariance and correlation between jointly distributed variables.
CO3	categorize and interpret simple linear regression and least square methods between twovariables.
CO4	describe methods of sampling and application of various statistical tests in testing hypotheses on data
CO5	build one-way and two-way classifications of analysis of variance, properties and assumptions,randomized block design and Latin square design problems
CO6	Perform model selection in a multiple linear regression modelling context.

CO Vs PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	2		
CO2	2	2	3			
CO3	3	2	3	2		
CO4	3	2	3	2		
CO5				2		
CO6	2					

REFERENCES:

1. Devore, J. L., "Probability and Statistics for Engineering & Sciences", 8th Edition, CengageLearning, 2014.
2. Gupta. S.C and Kapoor, V.K,. "Fundamentals of Mathematical Statistics", 12th Edition, SultanChand and Sons, New Delhi, 2020.
3. Johnson, R.A., Miller, I and Freund J., "Miller and Freund's Probability and Statistics for Engineers", 9th Edition, Pearson Education, Asia, 2016.
4. Rice, J. A., "Mathematical Statistics and Data Analysis", 3rd Edition, Cengage Learning, 2013.
5. Ross, S. M., "Introduction to Probability and Statistics for Engineers and Scientists", 6th Edition, Elsevier, 2020.

THERMODYNAMICS FOR BIOLOGICAL SYSTEMS **L T P C**
3 0 0 3

COURSE OBJECTIVES:

- Students will learn about the behavior of fluids, laws of thermodynamics, thermodynamic property relations and their application in different chemical processes

UNIT I THERMODYNAMIC LAWS **9**

Basic thermodynamic concepts, Energy and first Law; Reversibility and second Law; Review of Basic Postulates, equation of state and its applications, corresponding states, equilibrium criteria, Legendre Transformation and Maxwell's relations

UNIT II GIBBS PHASE RULE **9**

Phase rule, Stability of thermodynamic systems, first order phase transitions and critical phenomenon, single component phase diagrams, thermodynamic properties from volumetric and thermal data

UNIT III SOLUTION THERMODYNAMICS **9**

Partial molar properties, Gibbs-Duhem equation, fugacities in gas and liquid mixtures, activity coefficients, Ideal and Non-ideal solutions, azeotropes, Wilson, NRTL, and UNIQUAC equations, UNIFAC method.

UNIT IV PHASE EQUILIBRIA 9

Vapour Liquid Equilibrium involving low pressure, high pressures and multi component systems,VLE in ideal and non- ideal solutions, Henry's Law, Other phase equilibriums-SLE/LLE/VLLE.

UNIT V CHEMICAL EQUILIBRIA 9

Criteria of chemical reaction equilibrium in thermodynamic systems, Homogeneous gas and liquid phase reactions, heterogeneous reactions – phase and chemical equilibrium

TOTAL: 45 PERIODS

COURSE OUTCOMES:

Upon successful completion of this course, the student will be able to:

1. Understand the basic concepts, laws and different process related to chemical engineering thermodynamics.
2. characterize the chemical state of a system, and predict the equilibrium relations of the phases present as a function of physical conditions such as pressure and temperature
3. Understand the thermodynamic potential, its correlation and analyze and distinguish between ideal and non-ideal solution.
4. Understand and demonstrate the activity coefficient and activity property of solution.
5. Demonstrate the Chemical and phase equilibria equations
6. Understand the interrelationships between different thermodynamic properties and become familiar with the graphs to develop an intuition for the variation of these properties during various processes.

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	2	2			
CO2	2	1	2	2		
CO3	3	2	2			
CO4		2	1	2		
CO5	2	2				
CO6	2	2	2	2		

REFERENCES:

1. M. Smith, H. C. Van Ness and M. M. Abbott; Introduction to Chemical Engineering Thermodynamics, Tata-McGraw Hill (2003).
2. Sandler; Chemical, Biochemical, and Engineering Thermodynamics, John Wiley &Sons,New Delhi (2007).
3. Koretsky, M. D.; Engineering and Chemical Thermodynamics, John Wiley and Sons, NewDelhi (2004).
4. Callen, H. B. Thermodynamics and an Introduction to Thermostatistics; John iley andSons: New York (1985).
5. Tester, J. W., Modell, M., Thermodynamics and its Applications, Prentice-Hall, New Jersey(1996).
6. Rao., Y.V.C., Chemical Engineering Thermodynamics, University Press, Hyderabad,2005
7. Narayanan K.V"A Text Book of Chemical Engineering Thermodynamics "Prentice Hall ofIndia Pvt.Ltd.2001..

ENZYME ENGINEERING AND TECHNOLOGY

L	T	P	C
3	0	0	3

COURSE OBJECTIVES:

- To understand the IUBMB system of enzyme classification
- To know the catalytic activity of enzyme and its regulation
- To learn the enzyme immobilization; methods of immobilizing the enzymes and their kinetics
- To learn the significant features of the biochemical catalyst

UNIT I INTRODUCTION 9

Introduction to enzymes, Classification, Sources, Mechanism of enzyme action. Strategies of purification of enzymes, criteria of purity, molecular weight determination and characterization of enzymes, Enzymes of biological importance - Acetyl cholinesterase, angiotensin converting enzyme (ACE), ACE Inhibitors, HMG Co A reductase inhibitors, pseudo cholinesterase, 5'-nucleotidase (5NT), glucose-6-phosphate dehydrogenase (GPD), Isoforms, immunoreactivetrypsinogen (IRT) and chymotrypsin; amylase isoenzymes

UNIT II KINETICS OF ENZYME ACTION 9

Methods for investigating the kinetics of enzyme catalyzed reactions — Initial velocity Studies, Estimation of Michaelis Menten parameters, Effect of pH and temperature on enzyme activity, kinetics of inhibition. Modeling of rate equations for single and multiple substrate reactions

UNIT III IMMOBILIZED ENZYMES 9

Techniques of enzyme immobilization; kinetics of immobilized enzymes, effect of solute, partition & diffusion on the kinetics of immobilized enzymes, design and configuration of immobilized enzyme reactors; applications of immobilized enzyme technology, Economic argument for immobilization

UNIT IV ENZYMES IN FUNCTIONAL GROUP TRANSFORMATION 9

Functional group interconversion using enzymes (hydrolysis reaction, oxidation/reduction reactions, C-C bond formations), Retrosynthetic biocatalysis, Chemoenzymatic synthesis of natural products. Industrial process using enzymes for production of drugs, fine chemicals and chiral intermediates, Catalytic antibodies, The design and construction of novel enzymes, artificial enzymes, Biotransformation of drugs (hydroxylation of Steroids).

UNIT V APPLICATIONS OF ENZYMES 9

Enzymes in organic synthesis, Enzymes as biosensors, Enzyme for environmental application, Enzymes for molecular biology research, Enzymes for analytical and diagnostic applications.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

Upon successful completion of this course, students will be able to:

1. describe about the enzyme and its classification, reaction in order to proceed towards various concepts in biotechnology.
2. illustrate the enzyme kinetics which will provide the importance and utility of enzyme towards research.
3. discuss about the enzyme immobilization techniques and its application in food, pharmaceutical and chemical industries.
4. elaborate and explain how enzymes are used in a broad spectrum of industrial processes and describe how different enzymes can be modified for optimal performance in these processes.
5. Defend the enzyme applications in the field of organic synthesis, electronics, environment,

research and diagnostics.

6. acquire knowledge on biological, chemical, physical and mathematical principles which constitute the basis of bioengineering applications.

CO Vs PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	2	3	2	2		
CO2	3		2	2	1	
CO3	2	2	2	2		
CO4	2		1			
CO5	3	2		1		
CO6	2		2	2		

REFERENCES:

1. Bailey J.E., Ollis D.F. "Biochemical Engineering Fundamentals.". McGraw Hill, 2nd Edition1986.
2. Faber, Kurt "Biotransformations in Organic Chemistry: A Textbook.", 5th Edition. Springer,2008.
3. Palmer, Trevor. "Enzymes: Biochemistry, Biotechnology, Clinical Chemistry." 2nd Edition,East West Press, 2008.
4. Blanch H.W., Clark D. S., "Biochemical Engineering", Marcel Dekker, Inc. 2nd Edition, 1997.
5. Lee, James M., "Biochemical Engineering." PHI, 1st Edition, 1992.
   Yeh W.K., Yang H.C., James R.M., "Enzyme Technologies: Metagenomics, Biocatalysis and Biosynsthesis", Wiley- Blackwell, 1st Edition, 2010.

METABOLIC PROCESS AND ENGINEERING **L T P C**
3 0 0 3

COURSE OBJECTIVES:

- This course aims to provide fundamental and advanced knowledge in the development of microbial strain for bio production through metabolic engineering.

UNIT I CELLULAR METABOLISM **9**

Transport Processes – Fueling reactions – Glycolysis, fermentative pathways – TCA cycle andoxidative phosphorylation, anaplerotic pathways –Catabolism of fats, organic acids, and aminoacids - Biosynthesis of aminoacids, nucleic acids, and fatty acids – Polymerization – Growth energetics.

UNIT II REGULATION, MANIPULATION AND SYNTHESIS OF METABOLIC PATHWAY 9

Regulation of enzyme activity – Regulation of enzyme concentration – Regulation of metabolic networks — Regulation at the whole cell level — Metabolic pathway manipulations — Enhancement of Product yield and productivity – Extension of substrate range, product spectrum and novel products (Antibiotics, Polyketides, Vitamins) – Improvement of cellular properties – Metabolic pathway synthesis algorithm – Lysine biosynthesis.

UNIT III ANALYSIS AND METHODS FOR THE METABOLIC FLUX **9**

Metabolic flux map – Fluxes through the catabolic pathways in microbes– Metabolic flux analysis for determined, over-determined and under-determined systems –Sensitivity analysis – Direct flux determination from fractional label enrichment – Applications involving

complete enumeration of metabolite isotopomers – Carbon metabolite balances-GC-MS for metabolic flux analysis – genome wide technologies

UNIT IV GENOME BASED METABOLIC MODEL DEVELOPMENT 9

Development of Genomic scale metabolic model, Insilico Cells:studying genotype-phenotype relationships using constraint-based models, case studies in E. coli, S.cerevisiae metabolic network reconstruction methods, optimization of metabolic network, Identification of targets for metabolic engineering; software and databases for genome scale modeling

UNIT V ANALYSIS OF METABOLIC CONTROL AND INDUSTRIAL CASE STUDIES 9

Fundamental of Metabolic Control Analysis (MCA), MFA, and MPA and their application, Multi-substrate enzyme kinetics, Metabolic engineering examples for bio-fuel, bio-plastic and green chemical synthesis , Study of genome scale model in various systems for the production of green chemicals using software tools

TOTAL: 45 PERIODS

Upon successful completion of this course, students will be able to:

COURSE OUTCOMES:

1. highlights the engineering of the biology of microbes for maximal metabolite production.
2. summarize the cellular transport process, Regulation of enzyme activity and metabolic pathway synthesis algorithm.
3. acquire foundational technical knowledge of the production of biosynthetic products through recombinant DNA technology.
4. implement genome-scale metabolic modelling for design and evaluation of metabolic engineering strategies
5. Characterize metabolic flux map through the catabolic pathways in microbes and propose relevant metabolic engineering strategies
6. detail cellular modifications of metabolic, gene regulatory, and signalling processes/networks to achieve enhanced production of metabolites including pharmaceuticals, biochemicals and other biotechnology products.

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	1	2	2		
CO2	3		2	2		
CO3	2	2	2	2	2	
CO4	2		1			
CO5	3	1		1		
CO6	2	1	2	2		

REFERENCES

1. Christiana D. Smolke, " The Metabolic Pathway Engineering Handbook Fundamentals",CRC Press Taylor & Francis Group, 2010.
2. Cortossa, S., Aon, M.A., Iglesias, A.A. and Lloyd.D., "An Introduction to Metabolic andCellular Engineering", 2nd Edition,World Scientific Publishing Co, 2011
3. Curran, C.P., "Metabolic Processes and Energy Transfers - An Anthology of Current Thought", The Rosen Publishing group, Inc., 2006.
4. Nielsen, J., Villadsen, J. and Liden, G., "Bioreaction Engineering Principles",3rd Edition,Springer, 2011
5. Stephanopoulos, G.N., Aristidou, A.A. and Nielsen.J., "Metabolic Engineering - Principles and Methodologies", Elsevier Science, 2001.

PHARMACOGENOMICS

L T P C
3 0 0 3

COURSE OBJECTIVES:

Upon successfully completing this course, students will:

- Describe the fundamental concepts of pharmacogenomics.
- Recognize how new technologies, such next-generation sequencing, are affecting the development and use of pharmacogenomics.
- Aware of the significance of pharmacogenomics and its use in clinical practise.

UNIT I PHARMACOGENOMICS AND PERSONALIZED MEDICINE 9

Historical aspects of Pharmacogenetics, Pharmacogenetics and Populations, Monogenic and Multigenic Variations of Drug Responses, personalized medicine, strategies for application of pharmacogenomics to customize therapy, Barriers, Future Perspectives.

UNIT II PHARMACOGENETICS OF ENZYMES AND RECEPTORS 9

Pharmacogenetics of two clinically important polymorphic enzymes, CYP2D6 and TPMT, nuclear receptors, cell surface receptors, Future Perspectives on the Pharmacogenetics of Drug Metabolism, Nuclear Receptors, Cell Surface Receptors.

UNIT III PHARMACOGENETICS OF DRUG TRANSPORTERS 9

Organic anion and cation transporter polypeptide family – OATP-B, OATP-C, OATP-8, OATP-D, OATP-E, OATP-F, OATP-H, OATP-I, OATP-J, and PGT OAT1, OAT2, OAT3; OCT1, OCT2, OCT3, PepT and MRP families- MDR1, MDR3, BSEP, MRP1, MRP3, MRP4, MRP5, MRP6, MRP8 BCRP protein.

UNIT IV TECHNOLOGIES IN PHARMACOGENOMICS 9

Single Nucleotide Polymorphism, SNP Analysis Technologies, Biochemistries, Hybridization-Based Approaches - Enzyme-Based Approaches, Combined Hybridization/Enzymatic Approaches, Detection Methods, Platforms

UNIT V PHARMACOEPIGENETICS 9

General principles of epigenetic regulation – epigenetic mechanisms, DNA methylation, methylated cytosine binding proteins, histone modifications, coordination of epigenetic machinery, epigenetic functions, genetic imprinting, x inactivation, geneome defence, epigenetics and human disease - therapeutic applications – HDAC inhibitors, DNMT inhibitors, CpG Oligonucleotides and Immune Response, Designer Transcription Factors

TOTAL: 45PERIODS

COURSE OUTCOMES

The students will be able to

- Differentiate how individual genetic variations affect drug therapy outcomes, as well as therapeutic efficacy and toxicity.
- Describe how single nucleotide polymorphism functions as a biomarker for the assessment of disease, therapeutic response, and prognosis.
- As new tools based on genetics become available, use them, manage them, and decide on the best course of action.
- Use pharmacogenomics approaches to address issues in pharmaceutical care by using a specific pharmacological therapy.
- Be aware of the ethical and societal ramifications of genetic testing and the individualised pharmacological therapy that results from it.
- Recognize the effectiveness of different medications based on genetics and apply it to clinical research.

TEXTBOOKS

1. Pharmacogenetics: An Introduction and Clinical Perspective" edited by Joseph S. Bertino, et al. 2013.
2. Concepts in pharmacogenomics. Martin M. Zdanowicz. Bethesda, Md. American Society of Health-System Pharmacists, 2010.
3. Genomics and Pharmacogenomics in Anticancer Drug Development and Clinical Response Beverly A. Teicher, Federico Innocenti, Springer, USA, 2008.
4. Gene-Environment Interactions: Fundamentals of Ecogenetics Costa, LG and Eaton DL., Wiley Press, 2006.

REFERENCES

1. Pharmacogenomics Werner Kalow, Rachel F Tyndale, Urs A Meyer, Marcel Dekker Inc., USA, 2001.
2. Pharmacogenomics in Drug Discovery and Development Second Edition Edited by Qing Yan PharmTao, Santa Clara, Springer New York, 2014.
3. Pharmacogenomics Challenges and Opportunities in Therapeutic Implementation second edition Edited by Y. W. Francis Lam Stuart A. Scott. Academic Press, 2019.
4. Pharmacogenomics in clinical therapeutics edited by Loralie J. Langman and Amitava Dasgupta, John Wiley & Sons, Ltd, 2012.

CO – PO MAPPING						
PHARMACOGENOMICS						
Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3				2	
CO2			3			2
CO3	3	2				
CO4				2	3	
CO5	3					3
CO6		3				

SEMESTER I

ELECTIVE II

NANOBIOTECHNOLOGY **L T P C**
3 0 0 3

COURSE OBJECTIVES:

The course aims to

- provide fundamental concepts in nanomaterials and their use with biocomponents to synthesize and address larger systems.
- provides perspective for students who are interested in nanoscale physical and biological systems and their applications in medicine.

UNIT I INTRODUCTION TO NANOSTRUCTURES 9

Carbon Nanotubes (CNT), Fullerenes (C60, C300) Nano Peapods Quantum Dots and Semiconductor Nanoparticles, Metal-based Nanostructures (Iron Oxide Nanoparticles), Nanowires, Polymer-based Nanostructures (Dendrimers), Gold Nanostructures:(Nanorods, Nanocages, Nano shells)

UNIT II PROTEIN-BASED NANOSTRUCTURES 9

Nanomotors: Bacterial (E. coli) and Mammalian (Myosin family), Nano biosensors: Science of Self-assembly - from Natural to Artificial Structures (Biological Nanomotors - Biologically Inspired Hybrid Nanodevices) . Engineered Nanopores.

UNIT III NANOSTRUCTURES FOR ANALYTICS 9

Nanoparticles for Electrochemical Bioassays - Luminescent Semiconductor Quantum Dots in Biology - Nanoscale Localized Surface Plasmon Resonance Biosensors - Cantilever Array Sensors for Bioanalysis and Diagnostics - Bio nanoarrays

UNIT IV 3-D BIO -PRINTING (THREE-DIMENSIONAL BIO-PRINTING) 9

Introduction - History, principle and its components, Classification of 3D bio-printing techniques - Extrusion-based bio-printing, Droplet-based bio-printing, Laser-based bio-printing, Design Requirements for 3D Bio-printing- Magnetic Resonance Imaging, Computed Tomography, Computer-Aided Design Based Systems, 3D modelling software, Bio inks for 3D bio-printing - Applications of 3D Bio-printing and future trends.

UNIT V NANOMEDICINE AND NANOSENSING 9

Promising nanobiotechnologies for applications in medicine – Liposomes in nanomedicine – Therapeutic applications of nanomedicine – Nano- Sized carriers for drug delivery and drug carrier systems – Protein and peptide nanoparticles, DNA based nanoparticles, Lipid matrix nanoparticles for drug delivery – Design and development of bionanosensors using DNA, enzymes – Nanobiosensors for imaging and diagnosis.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

1. understand varied nanostructures
2. understand protein-based nanostructures
3. explore the nanotechnology for bioanalysis and diagnostics
4. understanding of most recent advances in Nanobiotechnology with novel Techniques.
5. know nano-based drug delivery and nanomedicine
6. explain the interaction between biomolecules and nanoparticle surface and its applications

CO-PO Mapping

Course outcome		Programme Outcomes (PO)					
		1	2	3	4	5	6
CO 1	understand varied nanostructures	2				1	
CO 2	Understand protein-based nanostructures	1	2			1	
CO 3	Explore the nanotechnology for bioanalysis and diagnostics	2		1	1		1
CO 4	Understanding of most recent advances in Nanobiotechnology with novel Techniques.	2	1	3	2	1	3
CO 5	know nano-based drug delivery and nanomedicine	1	2	3	1	1	3
CO6	explain the interaction between biomolecules and nanoparticle surface and its applications	1	2	1	1		

REFERENCES:

1. Nanobiotechnology: Concepts, Applications and Perspectives, Christ of M. Niemeyer (Editor), Chad A. Mirkin (Editor) , Wiley-VCH; 1 edition, 2004.
2. Nanobiotechnology II More Concepts and Applications Edited by Chad A. Mirkin and Christof M. Niemeyer. Wiley-VCH; 1 edition, 2007.
3. Nano Biotechnology: BioInspired Devices and Materials of the Future by Oded Shoseyovand Ilan Levy, Humana Press; 1 edition 2007.

4. 3D Bio-printing -Fundamentals, Principles and Applications, Ibrahim T. Ozbolat, Academic Press, (2016).
5. 3D Bio-printing in Regenerative Engineering, Principles and Applications, Ali Khademhosseini, Gulden Camci-Unal, 1st edition, CRC press, (2018).
6. Bio-Nanotechnology Concepts and applications. Madhuri Sharon, Maheshwar Sharon, Sunil Pandey and Goldie Oza, Ane Books Pvt Ltd, 1 edition 2012

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS **L T P C**
3 0 0 3

COURSE OBJECTIVES:

- To learn the principle parameters involved in drug absorption and disposition
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance
- To understand the pharmacokinetic parameters and its application as clinical pharmacokinetics

UNIT I BIOPHARMACEUTICS IN DRUG ABSORPTION AND DISTRIBUTION 9

Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non-per oral extra-vascular routes, Distribution of drugs, Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.

UNIT II BIOPHARMACEUTICS IN ELIMINATION 9

Drug metabolism, metabolic pathways, factors affecting metabolism, renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non- renal routes of drug excretion of drugs

UNIT III BIOAVAILABILITY AND BIOEQUIVALENCE 9

Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT IV PHARMACOKINETICS 9

Introduction to Pharmacokinetics, Pharmacokinetic models, One compartment open model Intravenous Bolus Injection – Intravenous infusion - Extra vascular administrations. Determination of pharmacokinetics parameters and their significance - Absorption Rate Constant (ka), Elimination Rate Constant (K) & Elimination Hal- life (t½), AUC, Cmax, and tmax. Apparent Volume of Distribution (Vd) & Renal Clearance (Q).

UNIT V CLINICAL PHARMACOKINETICS AND NONLINEAR PHARMACOKINETICS 9

Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states. Concept, Accumulation, Persistent and elimination factors. Calculation of dosage regimen following repetitive IV and oral administration. Nonlinear Pharmacokinetics - Introduction, factors causing Non-linearity, Michaelis-menton method of estimating pharmacokinetic parameters.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

The student will be able to

- Explain the various factors influencing the drug disposition, various pharmacokinetic parameters
- Design and interpret the bioavailability and bioequivalence of dosage forms.
- Identify the factors affecting the rate of drug absorption.
- Know about clinical pharmacokinetics
- Recognize the application of pharmacokinetics
- Be familiar with applications of Biopharmaceutics.

CO – PO MAPPING						
APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS						
CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO 1	3	**3**	**2**	**1**	**1**	**-**
CO 2	3	**3**	**2**	**1**	**1**	-
CO 3	3	**3**	**2**	**1**	**1**	-
CO 4	3	**3**	**2**	**1**	**1**	-
CO 5	3	**3**	**2**	**1**	**1**	-
CO 6	3	**3**	**2**	**1**	**1**	-

REFERENCES:

1. Shargel,L and Andrew, B.C. Yu. “Applied Biopharmaceutics & Pharmacokinetics”,7th Edition, The McGraw-Hill Companies, Inc, 2016.
2. Brahmankar, D.M. and Jaiswal, S.B. “Biopharmaceutics and Pharmacokinetics: a Treatise” ,3rd Edition, Vallabh Prakashan, 2015.
3. Chatwal, G.R. “Biopharmaceutics and Pharmacokinetics”, 2nd Edition, Himalaya Publishing House, 2014.
4. Rosenbaum, S. E. “Basic Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations”, 2 nd Edition, John Wiley & Sons, 2016.
5. Gibaldi, M. “Biopharmaceutics & Clinical Pharmacokinetics”, 4th Edition, Pharma Book Syndicate, 2016.
6. Jambhekar, S.S. and Philip, J. B. “Basic Pharmacokinetics” 2nd Edition, Pharmaceutical Press,2012

MOLECULAR MEDICINE

L T P C
3 0 0 3

COURSE OBJECTIVES:

- To provide an in-depth analysis of molecular medicine and mechanisms of diseases associated with Cardiac, renal endocrine and Nephrons.

UNIT I MOLECULAR BASIS OF DISEASES 9

Concepts pertaining to the Molecular basis of Infectious disease and metabolic disorders. Human genetics relevant to molecular medicine, single nucleotide polymorphisms, multiple gene polymorphisms, single and multi-gene diseases, gene-environment interactions in disease manifestation, genetic and physical mapping of human genome and identification of diseases gene.

UNIT II MOLECULAR BASIS OF GENETIC DISORDERS 9

Single-Gene Disorders, Autosomal Dominant Disorders -Polycystic Kidney Disease, Marfan's Syndrome, Huntington's Disease . Autosomal Recessive Disorders-Cystic Fibrosis, Phenylketonuria, Gaucher Disease, Ichthyosis, Tay–Sachs Disease.

UNIT III BACTERIAL INFECTIONS, ANTIBIOTIC ACTION AND DRUG RESISTANCE 9

Principles of Microbial Pathogenesis, Molecular basis of infection and pathogenesis of *Bacillus anthracis,* Mycobacterium spp., Mechanism of bacterial persistence and survival, Immunological response of Mycobacterial infection, Antibiotic action and resistance mechanisms, Drug resistance - origin (genetic and non-genetic), mechanisms**.**

UNIT IV MOLECULAR VIROLOGY 9

Molecular basis of Dengue infection and pathogenesis, molecular biology of Hepatitis A, B, C, D & E, and virulence, molecular Biology of HIV Infection, Influenza Virus, Measles, Mumps, Chicken Pox, Poliomyelitis, Human Papilloma virus (HPV), Rabies, Yellow fever and and Japanese Encephalitis. Anti-viral chemotherapy and viral vaccines.

UNIT V MOLECULAR DIAGNOSTICS 9

PCR-Based Methods for Mutation Detection, Alternative Methods for Mutation Detection and DNA Sequencingfor Disease Association, Microarray Approaches to Gene Expression Analysis, Methods for Analysis of DNA Methylation, Other Clinical Diagnostic Technologies:Flow Cytometry, Medical Cytogenetics, Fluorescence In Situ Hybridization, Immunohistochemistry, Laser Capture Microdissection (FFPE).

TOTAL: 45 PERIODS

COURSE OUTCOMES:

Upon successful completion of this course a students will be able to:

1. explain the organizational requirements for the translation of biomedical therapeutics from bench to bedside.
2. debate the impact translational research has had on human health and disease.
3. explain why pharmaceutical companies select particular drug or therapeutic targets for further study.
4. articulate the significance and potential of molecular medical advances in biomedical research.
5. apply the knowledge to decipher the mechanisms of molecular and cell biology.
6. synthesize the ideas for the improvement in the current technology.

CO Vs PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	1	2	2		
CO2	3		2	2		

CO3	3	2	2	2		
CO4	3		1			
CO5	3	1		1		
CO6	3	1	2	2		

REFERENCES:

1. Jameson, J. L., Francis, S.C., "Principles of Molecular Medicine", Human Press, 1998.
2. Ross, D.W. "Introduction to Molecular Medicine", 3 rd Edition, Springer, 2002.
3. Elles, R., Mountfield, R. (2011). Molecular Diagnosis of Genetic Diseases. Springer Publication..
4. Pasternak, J.J. "An Introduction to Human Molecular Genetics", 2 ndEdition, Wiley Liss, 2005.
5. Strachan, Tom and Andrew P. Read. "Human Molecular Genetics, Bios, 1996.

BIOGENERICS AND BIOPHARMACEUTICALS **L T P C**
3 0 0 3

COURSE OBJECTIVES:

- Introduce the students about biogenerics and biosimilars and their characterization using analytical methods.
- Correlate the conceptual learning of biopharmaceuticals with their therapeutic equivalence using case studies..

UNIT I BIOGENERICS INTRODUCTION 9

Definition: Generics and its advantages; Biogenerics and Biosimilars; why biosimilars are not (bio) generics; The advent of Biosimilars; The role of patents in the drug industry; Protein-based biopharmaceuticals; Manufacturing processes; Global market; International Non-proprietary Names (INN) nomenclature system biosimilars regulation (EU position, US pathways, Government initiatives)

UNIT II BIOSIMILARS AND ITS SCENARIO 9

Approved follow-on proteins/Biosimilars; Characteristics of high selling peptides and proteins,; Products with expired patents; Challenging originator's patents; Target products for FOB (follow-on biologics) /Biosimilars development peptides; Recombinant Non Glycosylated proteins; Recombinant glycosylated proteins; Industries dealing with biogenerics and its market value; World scenario; Indian scenario.

UNIT III CHARACTERIZATION OF BIOSIMILARS 9

Approaches to the characterization of biosimilars; Problems in characterizing biologics(Types of biologic, Peptides, Non-glycosylated proteins, Glycosylated proteins, Monoclonal antibodies); Equivalence issues; Post-translational modifications; Effect of microheterogeneity; Pharmacokinetics; Pharmacodynamics; and Clinical efficacy; Analytical Methods for the characterization of biosimilars (Chromatography, Protein sequencing, Mass Spectrometry, UV absorption, Circular dichroism, X-ray techniques, Nuclear magnetic resonance, Electrophoresis, Western blotting, Bioassays, ELISA, Immunoprecipitation and other procedures)

UNIT IV IMMUNOGENICITY OF BIOPHARMACEUTICALS 9

Immunogenicity of biopharmaceuticals: Immunogenicity; Factors contributing to immunogenicity, (product-related factors and host-related factors), consequence of immunogenicity to biopharmaceuticals; Measurement of immunogenicity.

UNIT V CASE STUDIES

Case Studies: Erythropoietin, Insulin, Somatotropin, Interleukin-2, Interferon, Granulocyte-macrophage-CSF, DNase, Factor VIIa, Factor IX, Factor VIII, Activated protein C, Tissue plasminogen activator, Monoclonal antibodies etc., Immunogenicity of biopharmaceuticals: Immunogenicity; Factors contributing.

TOTAL : 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to

1. Acquire knowledge about biogenerics, biosimilars, their nomenclature and regulations.
2. Update the patent and market scenario of follow on proteins.
3. learn about the characterization of biosimilars.
4. Attain the knowledge of immunogenicity of biopharmaceuticals
5. Have exposure on case studies dealing with immunogenicity of biopharmaceuticals
6. Apply the knowledge of biopharmaceuticals regulations, characterization and it Immunogenicity properties

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3		3			
CO2						
CO3	3	1	3	1		
CO4	3	2	1			
CO5	3	2	1			
CO6	3	1	3	1		

REFERENCES:

1. Niazi, Sarfaraz K. “Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues”. CRC Press, 2006.
2. Ho, Reedney J. Y., MiloGibaldi. “Biotechnology & Biopharmaceuticals ransforming Proteins andGenes into Drugs”, 2nd edition, 2013.
3. S. Lakshmana Prabu, TNK. Suriyaprakash, “Intellectual Property Rights”, InTech, Croatia, 2017.
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5. Rodney J Y Ho, MILO Gibaldi, Biotechnology & Biopharmaceuticals Transforming proteins and genes intodrugs, 1stEdition, Wiley Liss, 2003.
6. Prugnaud, Jean-Louis, Trouvin, Jean Hugues. “Biosimilars” Springer, 2012
7. Shein-Chung Chow. “Biosimilars: Design and Analysis of Follow-on Biologics” CRC Press, 2013.

ENVIRONMENTAL BIOTECHNOLOGY

L T P C
3 0 0 3

COURSE OBJECTIVES

- To study the environmental biotechnology is to understand the current applications of biotechnology to environmental quality evaluation, monitoring and remediation, of contaminated environments.

UNIT I CONCEPTS OF ENVIRONMENTAL BIOTECHNOLOGY 9

Definition, Historical background, scope applications of biotechnology. Biosorption - use of bacteria, fungi and algae in biosorption. Biodegradation of polychlorinated hydrocarbons.

Biodegradation of Pesticides. Microbial treatment of oil pollution. Genetically engineered organisms – Merits and demerits – Bio tools for environmental monitoring.

UNIT II BIOTECHNOLOGY AND VALUE ADDITION 9

Bio processes in waste treatment - Production of value added products from waste – single Cell Protein (SCP), ethanol, methane and hydrogen, amino acids, vitamins -Enzyme production from wastes – Biodegradable plastics - Environmental implications - .Biotechnology of Microbial composting - Biofertilizers- Biopesticides.

UNIT III BIOMEDICAL WASTE AND ITS MANAGEMENT 9

Biomedical waste: Introduction: definition, Classification, types and composition, Types of solids, liquids, sharps, blood and blood tissue, radioactive material, biological and chemical material. Documentation of Biomedical waste types and guidelines. Storage of hospital waste; Types of bags and containers used for storage; Segregation of biomedical waste into different type; Handling and transport of hospital waste. Transport of medical waste: Authorization and accidental spilling reporting.

UNIT IV ENVIRONMENT AND HEALTH 9

Concept, indicators and determinants of health- Bioindicators –Biomarkers –Biosensors – Biomonitoring. Environmental hazards-physical, chemical, biological, sociological & psychological. Concept, causation and natural history of disease. Principles of environmental control. National health policy and health situation in India

UNIT V ENVIRONMENTAL IMACT ASSEMENT 9

Environmental Impact Assessment (EIA): Concepts, objectives, origin & generalised approach to EIA. Methodologies of EIA and EIA guidelines (GOI Notification of 1994, 2006). Environmental Impacts, their types & important impacts to be considered in EIA . Environmental Impact Statement & Environmental Management Plan. Environmental Auditing: Concept & guidelines.

TOTAL : 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to

1. summarise biodegradation of polychlorinated hydrocarbons, pesticides through genetically engineered organisms.
2. illustrate bio processes in waste treatment and its end products
3. segregate biomedical waste into different type.
4. detail biomonitoring system in securing human health.
5. learn environmental impact assessment techniques.
6. recognise the environment and different processes that take place on Earth.

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1			3		3	
CO2		3				
CO3			3			
CO4	3					
CO5						
CO6				3	3	3

REFERENCES:

1. Alcamo, I.E.(1994). Fundamentals of Microbiology. The Benjamin/Cummings Pub. Co., USA.
2. Kumar, R. (1987). Environmental Pollution & Health Hazards in India. Ashish Pub.

House, New Delhi.
3. Abbasi, S.A. & Ramasami, E. (1999). Biotechnological Methods of Pollution Control. Unviersities Press (India) Ltd., Hyderabad.
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5. Chatterji. A.K., 2003. Introduction to Environmental Biotechnology. Prentice Hall of India Pvt. Ltd., New Delhi.

METABOLIC PROCESS AND ENGINEERING **L T P C**
3 0 0 3

COURSE OBJECTIVES:

- This course aims to provide fundamental and advanced knowledge in the development of microbial strain for bio production through metabolic engineering.

UNIT I CELLULAR METABOLISM 9

Transport Processes – Fueling reactions – Glycolysis, fermentative pathways – TCA cycle and oxidative phosphorylation, anaplerotic pathways –Catabolism of fats, organic acids, and aminoacids - Biosynthesis of aminoacids, nucleic acids, and fatty acids – Polymerization – Growth energetics.

UNIT II REGULATION, MANIPULATION AND SYNTHESIS OF METABOLIC PATHWAY 9

Regulation of enzyme activity – Regulation of enzyme concentration – Regulation of metabolic networks — Regulation at the whole cell level — Metabolic pathway manipulations — Enhancement of Product yield and productivity – Extension of substrate range, product spectrum and novel products (Antibiotics, Polyketides, Vitamins) – Improvement of cellular properties – Metabolic pathway synthesis algorithm – Lysine biosynthesis.

UNIT III ANALYSIS AND METHODS FOR THE METABOLIC FLUX 9

Metabolic flux map – Fluxes through the catabolic pathways in microbes– Metabolic flux analysis for determined, over-determined and under-determined systems –Sensitivity analysis – Direct flux determination from fractional label enrichment – Applications involving complete enumeration of metabolite isotopomers – Carbon metabolite balances-GC-MS for metabolic flux analysis – genome wide technologies

UNIT IV GENOME BASED METABOLIC MODEL DEVELOPMENT 9

Development of Genomic scale metabolic model, Insilico Cells:studying genotype-phenotype relationships using constraint-based models, case studies in E. coli, S.cerevisiae metabolic network reconstruction methods, optimization of metabolic network, Identification of targets for metabolic engineering; software and databases for genome scale modeling

UNIT V ANALYSIS OF METABOLIC CONTROL AND INDUSTRIAL CASE STUDIES 9

Fundamental of Metabolic Control Analysis (MCA), MFA, and MPA and their application, Multi- substrate enzyme kinetics, Metabolic engineering examples for bio-fuel, bio-plastic and green chemical synthesis , Study of genome scale model in various systems for the production of green chemicals using software tools

TOTAL: 45 PERIODS

COURSE OUTCOMES:

Upon successful completion of this course, students will be able to:

1. highlights the engineering of the biology of microbes for maximal metabolite production.
2. summarize the cellular transport process, Regulation of enzyme activity and metabolic pathway synthesis algorithm.
3. acquire foundational technical knowledge of the production of biosynthetic products through recombinant DNA technology.
4. implement genome-scale metabolic modelling for design and evaluation of metabolic engineering strategies
5. Characterize metabolic flux map through the catabolic pathways in microbes and propose relevant metabolic engineering strategies
6. detail cellular modifications of metabolic, gene regulatory, and signalling processes/networks to achieve enhanced production of metabolites including pharmaceuticals, biochemicals and other biotechnology products.

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	1	2	2		
CO2	3		2	2		
CO3	2	2	2	2	2	
CO4	2		1			
CO5	3	1		1		
CO6	2	1	2	2		

REFERENCES

1. Christiana D. Smolke, " The Metabolic Pathway Engineering Handbook Fundamentals",CRC Press Taylor & Francis Group, 2010.
2. Cortossa, S., Aon, M.A., Iglesias, A.A. and Lloyd.D., "An Introduction to Metabolic andCellular Engineering", 2nd Edition,World Scientific Publishing Co, 2011
3. Curran, C.P., "Metabolic Processes and Energy Transfers - An Anthology of Current Thought", The Rosen Publishing group, Inc., 2006.
4. Nielsen, J., Villadsen, J. and Liden, G., "Bioreaction Engineering Principles",3rd Edition,Springer, 2011
5. Stephanopoulos, G.N., Aristidou, A.A. and Nielsen.J., "Metabolic Engineering - Principlesand Methodologies", Elsevier Science, 2001.

SEMESTER II

ELECTIVE III

BIOINFORMATICS AND COMPUTATIONAL BIOLOGY **L T P C**

3 0 0 3

COURSE OBJECTIVES:

- To get familiarized with protein three dimensional structure, modeling, docking and molecular dynamics simulations
- Understand basics concepts in Machine learning, Systems Biology approaches and informatics techniques for protein identification

UNIT I GENOME BIOINFORMATICS 9

Automatic analysis, alignment, comparison and annotation of biological sequences; analysis of genome evolution and variation; molecular biology databases.

UNIT II PROTEIN STRUCTURE, MODELLING AND SIMULATIONS 9

Protein Structure Basics, Visualization, Prediction of Secondary Structure and Tertiary Structure, Homology Modeling, Protein Protein Interactions, Molecular Docking principles and applications, Molecular dynamics simulations.

UNIT III PHARMACOINFORMATICS 9

Molecular library management and virtual screening, computer assisted drug design and quantitative modelling of structure-activity relationships (QSAR and 3D-QSAR)

UNIT IV BIOMEDICAL COMPUTING 9

Clinical and healthcare information systems, biomedical imaging analysis, studying genotype-phenotype relationships and IT support systems for healthcare decision making.

UNIT V MACHINE LEARNING, SYSTEMS BIOLOGY AND OTHER ADVANCED TOPICS 9

Machine learning techniques: Artificial Neural Networks Applications in Protein secondary structure prediction, Hidden Markov Models for protein and gene families, Introduction to Systems Biology, Biological networks : Protein interaction and Gene regulatory networks and network motifs Single Input Module, Dense Overlapping Regulon and Feed Forward Loops, Microarrays and Clustering techniques for microarray data analysis, Informatics techniques for analysis of Mass spectrometry data : protein identification.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

Upon successful completion of this course, students will be able to:

1. summarise the basic procedures involved in genome assembly and annotation.
2. understand concepts in biological sequence analysis, next generation sequencing data analysis.
3. domonstrate the utility of molecular docking and simulations and analyze the results.
4. Illustrate machine learning techniques, networks in Systems biology, microarray data analysis and interpretation of results.
5. possess competence to unveil the relationship between the three-dimensional structure of bio-molecules and their biological activity.
6. have proficiency to handle macromolecular data of sequence and three-dimensional coordinates

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	1	2	2		
CO2	3		2	2	1	
CO3	2	2	2	2		
CO4	1	3	1		1	
CO5	3	1		1		
CO6	2	1	2	2		

REFERENCES:

1. David W. Mount. Bioinformatics - Sequence and Genome Analysis. Cold Spring Harbor Laboratory Press, New York
2. Finkelstein A, Ptitsyn O. Protein physics: a course of lectures. 2nd ed Academic Press. 2016.
3. PHILIP E. BOURNE Structural Bioinformatics / edited by Philip E. Bourne, Helge Weissig Hoboken, N.J. : Wiley-Liss, C 2003
4. TAYLOR, W. R. (Willie R.). Protein Geometry, Classification, symmetry and topology: a computational analysis of structure / William R. Taylor and András Aszódi Bristol:

Institute of Physics Pub., Once. 2005.
5. Leach, A. Molecular Modelling: Principles and Applications. 2a. ed. Harlow: Pearson Education, 2001.

BIOPROCESS ENGINEERING AND TECHNOLOGY **L T P C**
3 0 0 3

COURSE OBJECTIVES:

- Gain knowledge about the design of production of bioproducts under aerobic and anaerobic states, process economic and preparation of flow sheet of production process.
- State the enzyme kinetics, various factors regulating catalysis, different models for analyzing the enzyme kinetics, Immobilization and large-scale production of enzyme;

UNIT I BLACK BOX MODEL 9

Yield coefficients, black box stoichiometries, elemental balances, heat balance, degrees of reduction balances, systematic analysis of black box stoichiometries, and identification of gross measurement errors

UNIT II DESIGN OF FERMENTATION PROCESSES 9

Kinetics of substrate utilization, biomass growth and product formation, inhibition of cell growth and product formation. Design and operation of continuous cultures, chemostat in series, batch and fed batch cultures, total cell retention cultivation.

UNIT III MODELING OF VARIOUS FERMENTATION PROCESSES 9

Principles of model building for biotechnological processes, unstructured models on the population level, structured models on the cellular level, morphologically structured model, genetically structured models, cybernetic model, modeling of recombinant systems.

UNIT IV BIOREACTOR DESIGN & CONSTRUCTION 9

Basic design and construction of CSTR, bioreactor design of agitator / agitator motor, power consumption in aerated bioreactor, design of sparger, mixing time estimation, oxygen mass transfer capability in bioreactor, Removal of Heat in bioreactor, Main parameters to be monitored and controlled in fermentation processes.

UNIT V CASE STUDIES IN FERMENTATION DERIVED PRODUCTS 9

Case studies on Production of green chemicals, algal biofuels, recombinant Insulin. Case studies on medium design, reactor design & process optimization.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

Upon successful completion of this course the students will be able to:

1. Develop the capacity of production processes and control of aerobic and anaerobic systems, solve calculation based on process economy as well as to recognize the importance of flow sheet of the production system
2. Explain the kinetics of enzyme catalysed reaction in free and immobilized states.
3. organise the production of microbial enzymes and operate variables affecting the production process.
4. demonstrate about concept and criteria of scale up of laboratory process, Instrumentation and process control- offline and online.
5. Collect the proficient knowledge of translation of lab data to pilot level, they will be able to solve features involved in the scale up process, process monitoring and control**.**
6. plan a research career or to work in the biotechnology industry with strong foundation about bioreactor design and scale-up.

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	2	2		3		
CO2		3	2	3		

CO3		3		3		
CO4	3	3	2	3		
CO5		3	2	3		
CO6	2		3			

REFERENCES:

1. Shuler, M.L., Kargi F., "Bioprocess Engineering – Basic Concepts ", Prentice Hall,2nd Edition, 2015.
2. Pauline D., "Bioprocess Engineering Principles ". Elsevier, 2nd Edition, 2012.
3. Nielsen, J. and Villadsen, J. "Bioreaction Engineering Principles". Springer, 3rd Edition,2011.
4. Lydersen B.K., "Bioprocess Engineering Systems, Equipment and Facilities" , WileyBlackwell, 2nd Edition, 2010.
5. Bailey, J.E. and Ollis, D.F. "Biochemical Engineering Fundamentals", 2nd Edition, McGrawHill, 2017.
6. Stanbury, P.F., Stephen J.H., Whitaker A., "Principles of Fermentation Technology",Science & Technology Books, 2nd Edition, 2009.

MOLECULAR PHARMACOLOGY

L T P C
3 0 0 3

COURSE OBJECTIVES:

- know the basic molecular mechanism of drug action, receptors and their mode of action, endogenous bioactive molecules, drugs acting on various systems, toxicology applicable in drug discovery.

UNIT I MOLECULAR MECHANISM OF DRUG ACTION 10

Basic concepts in molecular pharmacology: agonists, antagonists and inverse agonists; potency, intrinsic activity and efficacy; Transducer mechanisms of receptors; Receptor occupancy theory and cellular signalling systems such as G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phosphatidylinositol. Ion channels and their modulators: measurement of binding and response, Voltage-gated ion channels. G protein-coupled receptors, G proteins and effectors, Mechanism of G protein-mediated signalling: - Wnt, hedgehog and notch; Signal transduction through tyrosine kinases; Receptors regulating gene expression.

UNIT II RECEPTORS AND THEIR MODE OF ACTION 8

Angiotensin receptors Excitatory amino acid receptors Kinin receptor, Adrenoceptors, Low molecular weight heparins, hirudins and GP IIB/IIIa receptor antagonists, Cholinergic receptors, Dopamine receptors, Serotonin receptors, Hormone receptors, GABA and Benzodiazepine receptors, Opioid receptors, Purinergic receptors, Glutamate receptors.

UNIT III BIOACTIVE MOLECULES 8

Endogenous bioactive molecules: Cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme and protein kinase C, arachidonic acid metabolites, COX- 2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators.

UNIT IV OVERVIEW OF DRUGS ACTING ON VARIOUS SYSTEMS 10

Central nervous system, Autonomic nervous system, Autacoids, Analgesic, Antipyretic, and Anti-inflammatory Agents, Renal and cardiovascular system, Anti Infective agents, Hormones, Hematopoietic agents.

UNIT V TOXICOLOGY 9

Principles of toxicology, Physicochemical, Biochemical and genetic basis of toxicity, principles of toxicokinetics, mutagenesis and carcinogenesis, Acute, sub-acute and chronic toxicity studies according to guidelines. Guidelines and regulatory agencies – CPCSEA, OECD, FDA, ICH, FHSA, EPA, EEC, WHO.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

1. To describe basic concepts in molecular pharmacology of several agonists: antagonists transducer mechanisms of receptors and receptors regulating gene expression.
2. To illustrate various receptor mechanism required for drug discovery Process.
3. To detail endogenous bioactive molecules and neuro transmitters essential for drug development procedure.
4. To highlight drugs acting on Central nervous system, Autonomic nervous system to understand the mechanism of drug action.
5. To explain the principles of toxicology, guidelines and regulatory agencies – CPCSEA, OECD, FDA, ICH, FHSA, EPA, EEC, WHO.
6. To summarize various applications of drugs in human health care and safety regulations

CO Vs PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	2	3	2	2		
CO2		3	2	2		
CO3	2	2	2	2	2	
CO4		2	1			
CO5	3	3		1		
CO6	2	2	2	2		

REFERENCES:

1. Laurence Brunton, Bjorn Knollmann, RandaHilal-Dandan, “Goodman and Gilman’s: The Pharmacological basis of therapeutics”, McGraw-Hill Education / Medical, 13th edition, 2017.
2. Tripathi, K.D. “Essentials of Medical Pharmacology”, Jaypee Brothers Medical Publishers, 8 th edition, 2018.
3. RS Satoskar Nirmala Rege SD Bhandarkar, “Pharmacology and PharmacoTherapeutics”, Elsevier India, 26 th edition, 2020.
4. Francesco Clementi (Editor), Guido Fumagalli (Editor), “General and Molecular Pharmacology: Principles of Drug Action”, Wiley, 1st edition, 2015.
5. Karen Whalen, “Lippincott Illustrated Reviews: Pharmacology”, Lippincott Williams and Wilkins, 7th Edition, 2019.
6. James Ritter, Rod Flower, Graeme Henderson, Yoon Kong, Loke David, Mac Ewan Humphrey Rang “Rang and Dales Pharmacology”, Elsevier, 9 th edition, 2018.
7. Katzung, B.G., “Basic and Clinical Pharmacology”, 14th Edition, McGraw Hill 2017.

BIOCONJUGATE TECHNOLOGY

L T P C
3 0 0 3

COURSE OBJECTIVES:

- At the end of the course, the student would have learnt about enzymes, nucleic acids and how to modify them for target specificity. Student also gets familiarized with the industrial applications of this technology.

UNIT I FUNCTIONAL TARGETS 9

Modification of Amino Acids, Peptides and Proteins – Modification of sugars, polysaccharides and glycoconjugates – modification of nucleic acids and oligonucleotides.

UNIT II CHEMISTRY OF ACIVE GROUPS 9

Amine reactive chemical reactions – Thiol reactive chemical reactions – carboxylate reactive chemical reactions – hydroxyl reactive chemical reactions – aldehyde and ketone reactive chemical reactions – Photoreactive chemical reactions.

UNIT III BIOCONJUGATE REAGENTS 9

Zero length cross linkers – Homobifunctional cross linkers – Heterobifunctional cross linkers – Trifunctional cross linkers – Cleavable reagent systems – tags and probes.

UNIT IV ENZYME AND NUCLEIC ACID MODIFICATION AND CONJUGATION 9

Properties of common enzymes – Activated enzymes for conjugation – biotinylated enzymes – chemical modification of nucleic acids – biotin labeling of DNA- enzyme conjugation to DNA – Fluorescent of DNA.

UNIT V BIOCONJUGATE APLICATIONS 9

Preparation of Hapten-carrier Immunogen conjugates - antibody modification and conjugation – immunotoxin conjugation techniques – liposome conjugated and derivatives-Colloidal –gold-labeled proteins – modification with synthetic polymers.

TOTAL : 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

1. Acquire the knowledge of modifying functional agents such as proteins, sugars, etc.,
2. Apply the knowledge of chemical reactivity of active groups
3. Know about the conjugate reagents
4. Attain the knowledge of enzyme and nucleic acids modification and conjugation
5. Have the knowledge of bioconjugate applications
6. Apply the knowledge of bioconjugate and its applications

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	1	3	2		
CO2	3					
CO3	3			1		
CO4	3		1	1		
CO5	3	2	2	1		
CO6	3	1	3	2		

REFERENCES:

1. Chemistry of bioconjugates : synthesis, characterization, and biomedical applications / edited by Dr. Ravin Narain, Department of Chemical and Materials Engineering, University of Alberta, Edmonton, Alberta, Canada.

2. Hermanson, G.T. “Bioconjugate Techniques”. Academic Press 3rd edition, 2013.
3. Sam Massa and Nick Devoogdt (eds.), Bioconjugation: Methods and Protocols, Methods in Molecular Biology, vol. 2033, Springer Science Business Media, LLC, part of Springer Nature 2019.
4. Sonny S. Mark (ed.), Bioconjugation Protocols: Strategies and Methods, Methods in Molecular Biology vol. 751, DOI 10.1007/978-1-61779-151-2_1, Springer Science+Business Media, LLC 2011.
5. Chrostof M.Niemeyer (Eds) Methods in Molecular Biology. 283. Bioconjugation Protocols Strategies and Methods. Humana Press.

SEMESTER II, ELECTIVES IV

BIO-ENTREPRENEURSHIP **L T P C**
3 0 0 3

COURSE OBJECTIVES:

The main objectives of this course are to:

- enable the students to understand the sources of innovation opportunities and development of the skills to identify and analyze these opportunities for bioentrepreneurship and innovation.
- develop personal skills set for creativity, innovation and entrepreneurship and specific
- concepts and tools for combining and managing creativity in organization

UNIT I BASICS OF BIOENTREPRENEURSHIP 9

Introduction to bioentrepreneurship – Biotechnology in a global scale, Scope in Bioentrepreneurship, Importance of entrepreneurship. Meaning of entrepreneur, function of an entrepreneur, types of entrepreneur, and advantages of being entrepreneur. Innovation – types, out of box thinking, opportunities for Bioentrepreneurship. Entreprenuership development programs of public and private agencies (MSME, DBT, BIRAC, Startup and Make in India).

UNIT II MANAGEMENT, ACCOUNTING AND FINANCE 9

Management principles of Henry Fayol. Business plan preparation: business feasibility analysis by SWOT, socio-economic costs benefit analysis, Sources of financial assistance – making a business proposal, approaching loan from bank and other financial institutions, budget planning and cash flow management, basics in accounting practices - balance sheet, P&L account, double entry book keeping, and estimation of income, expenditure and Income tax.

UNIT III KNOWLEDGE CENTRE AND R & D 9

Knowledge centers - Universities, innovation centre, research institutions and business incubators. R&D - technology development and upgradation, assessment of technology development, managing technology transfer, industry visits to successful bio-enterprises, regulations for transfer of foreign technologies, quality control, technology transfer agencies,

UNIT IV MEDIUM & SMALL SCALE INDUSTRY 9

Definition, characteristics, need and rationale, objectives, scope and advantages of small scale industries. Types of bioindustries – Pharma, Agri and Industry. Biofertilizers production - Azospirillium, Azolla, Cyanobacteria and its applications. Biopecticides production - Bacterial, fungal, viral and plant insecticides. Sericulture. Apiculture. Dairy farming. Single Cell Protein Production and applications.

UNIT V MARKETING AND HUMAN RESOURCE DEVELOPMENT 9

Assessment of market demand for potential product(s) of interest, Market conditions, segments, prediction of market changes, identifying needs of customers including gaps in the market. Branding issues, developing distribution channels – franchising policies, promotion, advertising, branding and market linkages. Marketing of agro products. Recruitment and selection process, leadership skills, managerial skills, organization structure, training, team building and teamwork.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

On the successful completion of the course, student will be able to:

1. know the legal and financial conditions for starting a business venture
2. explain the importance of marketing and management in small businesses venture and can interpret their own business plan
3. identify the elements of success of bioentrepreneurial scheme and projects
4. Can able to specify the basic performance indicators of various entrepreneurial activities.
5. Summarise the regulations for transfer of foreign technologies
6. Student will be able to analyse the business environment in order to identify business opportunities.

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	1		1	2	2	3
CO2	1			2	2	3
CO3		1		2	2	3
CO4	1				1	3
CO5	1			1	2	3
CO6	3	1	2	2		

REFERENCES

1. Principles of Management", PC Tripati, PN Reddy,–Tata Mc Graw Hill
2. Management Fundamentals", Robert Lusier – Concepts, Application, Skill Development" Thomson
3. Entrepreneurship Development" S S Khanka , S Chand & Co
4. Dynamics of Entrepreneurial Development & Management" Vasant Desai Himalaya Publishing House

BIOMATERIALS AND TISSUE ENGINEERING L T P C

3 0 0 3

COURSE OBJECTIVES:

The objective of this course is to

- Acquire knowledge on biomaterials and its applications
- Enable the students to learn the aspects of tissue engineering
- Get information about the applications of tissue engineering

UNIT I BIOMATERIALS 9

Biomaterials: Properties of biomaterials-Surface, bulk, mechanical and biological- Scaffolds & tissue engineering - Types of biomaterials-biological and synthetic materials- Biopolymers-Applications – Modifications – Nanotechnology in biomaterials.

UNIT II BASIC BIOLOGY OF STEM CELLS 9

Stem Cells: Introduction- hematopoietic differentiation pathway -Potency and plasticity of stem cells- Stem Cell markers- Types and sources of stem cell with characteristics: embryonic- adult- haematopoietic- fetal- cord blood-placenta- bone marrow-primordial germ cells- cancer stem cells.

UNIT III TISSUE ENGINEERING 10

Introduction to tissue engineering: Basic definition-current scope - cell numbers and growth rates- measurement of cell characteristics –morphology- number viability- motility and functions. Measurement of tissue characteristics - appearance- cellular component-ECM component- physical properties.

UNIT IV TISSUE REPAIR 8

Tissue types and Tissue components, Tissue repair and Engineering -wound healing and sequence of events - Cell-Matrix- Cell-Cell Interactions - telomeres and Self renewal-Control of cell migration in tissue engineering.

UNIT V CLINICAL APPLICATIONS AND ETHICAL ISSUES 9

Stem cell therapy-Molecular therapy - In vitro Organogenesis-Neuro degenerative diseases-spinal cord injury- heart disease- diabetes- burns and skin ulcers- muscular dystrophy-orthopaedic applications - Patent protection and regulation of tissue engineered products-ethical issues.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

Upon completion of this course, the students would get

1. Awareness about the properties and broad applications of biomaterials
2. Overall exposure to the role of tissue engineering and stem cell therapy in organogenesis
3. Knowledge of tissue engineering principles
4. Ability to understand the tissue components and tissue repair
5. Opportunity to get familiarized with the stem cell characteristics and their relevance in medicine
6. to know the applications of Biomaterials and Tissue Engineering

CO – PO MAPPING						
BIOMATERIALS AND TISSUE ENGINEERING						
CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO 1	3	**3**	**2**	**-**	**1**	**-**
CO 2	3	**3**	**2**	**-**	**1**	-
CO 3	3	**3**	**2**	**-**	**1**	-
CO 4	3	**3**	**2**	**-**	**1**	-
CO 5	3	**3**	**2**	**-**	**1**	-
CO 6	3	**3**	**2**	**-**	**1**	-

REFERENCES:

1. Bernhard O.Palsson, Sangeeta N.Bhatia, ”Tissue Engineering” Pearson Publishers 2009.
2. Meyer, U.; Meyer, Th.; Handschel, J.; Wiesmann, H.P. Fundamentals of Tissue Engineering and Regenerative Medicine. 2009.
3. R. Lanza, J. Gearhart et al (Eds), Essential of Stem Cell Biology, Elsevier Academic press, 2006.

4. J. J. Mao, G. Vunjak-Novakovic et al (Eds), Translational Approaches in Tissue Engineering & Regenerative Medicine" Artech House, INC Publications, 2008
5. Bernard N. Kennedy (editor), Stem cell transplantation, tissue engineering, and cancer applications, New York: Nova Science Publishers, 2008.
6. Raphael Gorodetsky, Richard Schäfer Stem cell- based tissue repair, Cambridge: RSC publishing, 2011.

ADVANCES IN OMICS SCIENCES AND TECHNOLOGY **L T P C**
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COURSE OBJECTIVES

The course aims to,

- Provide advanced theoretical knowledge on the organization and function of genome
- Understand the principles of functional genomic analyses
- Have knowledge on the advanced methods and approaches in proteomics.

UNIT I MICROARRAYS IN GENOMICS 9

Microarrays, types, Designing and production of microarrays; cDNA microarray technology; Oligonucleotide arrays; Sample preparation, labeling, hybridization, generation of microarray data. Transcriptomics using cDNA and oligonucleotide arrays.

UNIT II NEXT GENERATION SEQUENCING TECHNOLOGIES 9

Overview of Next Generation Sequencing (NGS) technologies; Principles of NGS by Roche/454, Illumina, Life Technologies, Pacific Biosciences, Ion Torrent technologies; Applications of NGS to disease diagnosis and personalized medicine.

UNIT III PROTEIN MICROARRAYS AND YEAST TWO-HYBRID SYSTEM 9

Types of protein arrays; Protein microarray fabrication; Experimental analysis of proteins arrays. Data acquisition and processing; Applications of protein microarray types. Principles and methods in yeast two-hybrid system, Advances in yeast two hybrid system and its applications.

UNIT IV TWO-DIMENSIONAL GEL ELECTROPHORESIS OF PROTEINS 9

Sample preparation, First-dimension IEF with IPG; Second dimensional separation of proteins; Image analysis of 2-DE gels; DIGE, Protein expression profiling and comparative proteomics of complex proteomes using 2-DE.

UNIT V MASS-SPECTROMETRY 9

Basics of Mass-spectrometry (MS) and bimolecular analysis; Common ionization methods for peptide/protein analysis; Principles of Time of Flight (TOF), Ion Trap (IT), and Orbitrap mass analyzers; Mass spectrometry based proteomics: MALDI-TOF, Nano-LC-MS; Gas-chromatography coupled to Mass spectrometry; Mass-spectrometry analysis of Post-Translational Modifications of proteins.

TOTAL: 45 PERIODS

COURSEOUTCOMES:

At the end of the course the student will be able to,

- Understand the designing and application of microarrays in genomics.
- Have knowledge in next generation sequencing technologies and their use in diagnosis and personalized therapy.

- Have exposure to protein analysis using high end technology
- Acquire the knowledge of 2D gel Electrophoresis of proteins
- Understand the concepts of mass spectrometry in protein analysis
- Attain the knowledge of micro array , sequencing, 2D gel electrophoreses and mass spectrometry techniques in proteins and genomics

CO - PO mapping

Course outcomes	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	1	2	2		
CO2	3		2	2		
CO3	3	2	2	2		
CO4	3		1			
CO5	3	1		1		
CO6	3	1	2	2		

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1. Schena M. (2000) DNA Microarrays - A Practical Approach. Oxford University Press.
2. Rinaldis E. D. and Lahm A (2007) DNA Microarrays. Horizon bioscience.Causton,H.C.
3. Muller H. J. and Roder T. (2006) Microarrays. Elsevier Academic Press.
4. Causton H. C., Quackenbush J., and Brazma A. (2004) A Beginner's Guide.
5. Schena M. (2005) Protein Microarrays. Jones and Bartlett Publishers.
6. O'Connor C. D. and Hames B. D. (2008) Proteomics. Scion Publishing Ltd.
7. Hoffman E. D. and Stroobant V. (2007) Mass Spectrometry – Principles and Applications, JohnWiley & Sons Ltd.