DEPARTMENT OF BIOTECHNOLOGY

ANNA UNIVERSITY, CHENNAI

Vision:

The Department of Biotechnology is committed to evolve as a world class science and technology centre by integrating quality and ethics in teaching and research

Mission:

The mission of the department is

- Empowering students with a unique multidisciplinary learning experience and fostering the young minds to develop as a researcher, entrepreneur, etc.
- Enhancing academic and industrial collaborative research initiatives for the development of biotechnological, food and therapeutic products.
- Emphasizing and equipping the students towards innovative industrial and research developments.
- Serving the society with utmost commitment, integrity, enthusiasm, and dedication.

ANNA UNIVERSITY, CHENNAI: 600 025

UNIVERSITY DEPARTMENTS
M.TECH BIOPHARMACEUTICAL TECHNOLOGY
CHOICE BASED CREDIT SYSTEM (CBCS)

PROGRAMME EDUCATIONAL OBJECTIVES (PEOs)

Masters of Biopharmaceutical Technology curriculum is designed to prepare the graduates to

1. Demonstrate technical expertise and problem-solving skills to contribute effectively in biopharmaceutical technology.
2. Inculcate scientific and professional ethics, good communication and teamwork skills with a multidisciplinary approach able to address health related problems to broader social context.
3. Comprehend, evaluate, design and develop new products and solutions for the wellbeing of mankind.
4. Engage in lifelong learning, demonstrating the ability to adapt to evolving technologies and emerging trends in their biopharmaceuticals field through continuous professional development.
5. Exhibit their leadership potential and be able to take managerial roles, exhibit their capacity to lead and guide projects and teams effectively.

Programme Outcomes (PO)

PO	Programme Outcomes
1.	Ability to independently carry out research/investigation and development work to solve practical problems.
2.	Ability to write and present a substantial technical report/document.
3.	Ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor programme.
4.	Ability to demonstrate skills to employ modern technology, software and equipment to analyze problems. The post graduate will be adept at performing experiments in modern biopharmaceutical and biotech industries where advanced tools would be used for developing health care solutions.
5.	Ability to demonstrate knowledge of professional and ethical responsibilities to interact in industry, business and society in a professional and ethical manner to uphold the morality of the society. They will demonstrate the ability and requirements to sense the needs of the nation and their role in nation building.
6.	Ability to lead and function in a multidisciplinary team to transform innovative ideas into reality, establish themselves as successful professionals and entrepreneurs to show the way in healthcare industries

MAPPING OF PROGRAMME EDUCATIONAL OBJECTIVE WITH PROGRAMME OUTCOMES

PEO	PROGRAMME OUTCOMES					
	PO1	PO2	PO3	PO4	PO5	PO6
1	**3**	**-**	**3**	**3**	**-**	**2**
2	**2**	**2**	**3**	**3**	**3**	**3**
3	**3**	**3**	**3**	**3**	**1**	**3**
4	**3**	**-**	**3**	**3**	**-**	**2**
5	**1**	**-**	**1**	**2**	**3**	**3**

PROGRAM ARTICULATION MATRIX
MAPPING OF COURSE OUTCOMES WITH PROGRAMME OUTCOMES

Year	Semester	Course name	PO					
			1	**2**	**3**	**4**	**5**	**6**
I	I	Applied Probability and Statistics						
		Research Methodology and IPR						
		Formulation Technology	2.8	1.8	2.6	2	2.8	2.8
		Molecular Pharmacology	2	1	1.6	1.6	3	2
		Formulation Technology Laboratory	2.8	1.8	2.6	2	2.8	2.8
	II	Applied Biopharmaceutics and Pharmacokinetics	2.6	1	2.6	2	2	2.6
		Immunopharmacology	2	2.4	2.4	2	1	1
		Animal cell culture technology	3	3	2.5	2	2.5	2.5
		Regulatory affairs in the Pharmaceutical Industry	1.4	1.6	1.6	1.8	2.4	1.75
		Immunopharmacology Laboratory	2.3	2.0	3.0	2.6	1.6	1.6
II	III	Animal cell culture technology Laboratory	2.3	-	1.6	2	3	3
		Sophisticated Analytical Techniques Laboratory	2.6	3	2.3	2.6	2.6	2.3
		Computational methods in drug discovery Laboratory	3	2	2.6	2.3	1.6	1
		Project Work I	3	2	3	3	2	3
	IV	Project Work II	3	2.67	3	3	2	3

ANNA UNIVERSITY, CHENNAI: 600 025
UNIVERSITY DEPARTMENTS
REGULATIONS - 2023
M.TECH BIOPHARMACEUTICAL TECHNOLOGY
CHOICE BASED CREDIT SYSTEM (CBCS)
CURRICULUM AND SYLLABI FOR I TO IV SEMESTER

SEMESTER I

S. NO	CODE NO.	COURSETITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1	MA3158	Applied Probability and Statistics	FC	4	0	0	4	4
2	RM3151	Research Methodology and IPR	RMC	2	1	0	3	3
3	BP3101	Formulation Technology	PCC	4	0	0	4	4
4	BP3151	Molecular Pharmacology	PCC	3	0	0	3	3
5		Professional Elective I	PEC	3	0	0	3	3
6		Professional Elective II	PEC	3	0	0	3	3
7.		Professional Elective III	PEC	3	0	0	3	3
PRACTICALS								
8.	BP3111	Formulation Technology Laboratory	PCC	0	0	4	4	2
			TOTAL	**22**	**1**	**4**	**27**	**25**

SEMESTER II

S. NO	CODE NO.	COURSETITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1	BP3201	Applied Biopharmaceutics and Pharmacokinetics	PCC	3	0	0	3	3
2	BP3202	Immunopharmacology	PCC	3	0	0	3	3
3	BT3252	Animal Cell Culture Technology	PCC	3	0	0	3	3
4	BP3203	Regulatory affairs in the Pharmaceutical Industry	PCC	3	0	0	3	3
5		Professional Elective IV	PEC	3	0	0	3	3
6		Professional Elective V	PEC	3	0	0	3	3
PRACTICALS								
7.	BP3211	Immunopharmacology Laboratory	PCC	0	0	6	6	3
			TOTAL	18	0	6	24	**21**

SEMESTER III

S. NO	CODE NO.	COURSETITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
PRACTICALS								
1.	BT3261	Animal Cell Culture Technology Laboratory	PCC	0	0	6	6	3
2.	BT3361	Sophisticated Analytical Techniques Laboratory	PCC	0	0	6	6	3
3.	BP3311	Computational Methods in Drug Discovery Laboratory	PCC	1	0	4	5	3
4.	BP3312	Project Work I	EEC	0	0	12	12	6
			TOTAL	1	0	28	29	**15**

SEMESTER IV

S. NO.	COURSE CODE	COURSE TITLE	CATEGOR Y	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
PRACTICALS								
1.	BP3411	Project Work II	EEC	0	0	24	24	12
			TOTAL	**0**	**0**	**24**	**24**	**12**

TOTAL NO. OF CREDITS: 73

PROFESSIONAL ELECTIVES

S. NO.	COURSE CODE	COURSE TITLE	CATEGOR Y	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
1.	BP3054	Biogenerics and Biopharmaceuticals	PEC	3	0	0	3	3
2.	BT3052	Environmental Biotechnology	PEC	3	0	0	3	3
3.	BT3053	Enzyme Engineering and Technology	PEC	3	0	0	3	3
4.	BT3057	Nanobiotechnology	PEC	3	0	0	3	3
5.	BT3056	Molecular pathogenesis of infectious diseases	PEC	3	0	0	3	3
6.	BT3058	Plant Design and Practice	PEC	3	0	0	3	3
7.	BT3059	Human Heredity and Genetics	PEC	3	0	0	3	3

8.	BP3052	Clinical Trials and bioethics	PEC	3	0	0	3	3
9.	BP3051	Chemistry of Natural Products	PEC	3	0	0	3	3
10.	BC3251	Structural Biology	PEC	3	0	0	0	3
11.	BT3253	Techniques in Molecular Biology and Genetic Engineering	PEC	3	0	0	3	3
12.	BT3060	Biosensors and Diagnostic applications	PEC	3	0	0	3	3
13.	BT3251	Advanced Bioseparation Technology	PEC	3	0	0	3	3
14.	BT3054	GMP and validation in Bioprocess industries	PEC	3	0	0	3	3
15.	BP3055	Molecular Medicine and Mechanism	PEC	3	0	0	3	3
16.	BC3051	Synthetic Biology	PEC	3	0	0	3	3
17.	BP3001	Bioconjugate Technology and Applications	PEC	3	0	0	3	3
18.	BT3051	Applied Genomics and Proteomics	PEC	3	0	0	3	3
19.	BT3055	Metabolic Engineering	PEC	3	0	0	3	3
20.	BP3002	Advances in Pharmacogenomics	PEC	3	0	0	3	3
21.	BP3003	Conventional and rational Drug Discovery Strategies	PEC	3	0	0	3	3
22.	BP3053	Molecular diagnostics	PEC	3	0	0	0	3

LIST OF PROFESSIONAL CORE COURSES (PCC)

S. NO.	COURSE CODE	COURSE TITLE	CATEGORY	PERIODS PER WEEK			CREDITS
				L	T	P	
1.	BP3101	Formulation Technology	PCC	4	0	0	4
2.	BP3151	Molecular Pharmacology	PCC	3	0	0	3
3.	BP3111	Formulation Technology Laboratory	PCC	0	0	4	2
4.	BP3201	Applied Biopharmaceutics and Pharmacokinetics	PCC	3	0	0	3
5	BP3202	Immunopharmacology	PCC	3	0	0	3
6	BT3252	Animal cell culture technology	PCC	3	0	0	3
7	BP3203	Regulatory affairs in the Pharmaceutical Industry	PCC	3	0	0	3
8	BP3211	Immunopharmacology Laboratory	PCC	0	0	6	3
9	BT3261	Animal cell culture technology Laboratory	PCC	0	0	6	3
10	BT3361	Sophisticated Analytical Techniques Laboratory	PCC	0	0	6	3
11	BP3311	Computational methods in drug discovery Laboratory	PCC	1	0	4	3

LIST OF EMPLOYABILITY ENHANCEMENT COURSES (EEC)

S. NO.	COURSE CODE	COURSE TITLE	CATEGORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	C		
1.	BP3312	Project Work I	EEC	0	0	12	12	6
2.	BP3411	Project Work II	EEC	0	0	24	24	12
TOTAL CREDITS							**18**	

CREDIT SUMMARY

	M.TECH BIOPHARMACEUTICAL TECHNOLOGY					
	SUBJECT AREA	CREDITS PER SEMESTER				CREDITS TOTAL
		I	II	III	IV	
1.	FC	4	-	-	-	4
2.	PCC	9	15	9	-	33
3.	PEC	9	6	-	-	15
4.	RMC	3	-	-	-	3
5.	EEC	-	-	6	12	18
6.	**TOTAL CREDIT**	**25**	**21**	**15**	**12**	**73**

SEMESTER I

MA3158 APPLIED PROBABILITY AND STATISTICS L T P C
4 0 0 4

OBJECTIVE

The Course aims to provide knowledge on the

- basics of random variables with emphasis on the standard discrete and continuous distributions.
- concepts of sampling distributions and the test statistics.
- statistical methods and concepts by which real life problems are analyzed.

UNIT I PROBABILITY THEORY 12

Random variables – probability density and distribution functions-moment generating and characteristic functions – Binomial, Poisson, Normal distributions and their applications.

UNIT II SAMPLING THEORY 12

Sampling distributions – Standard error – t, F, Chi square distributions – applications.

UNIT III ESTIMATION THEORY 12

Interval estimation for population mean, standard deviation, difference in means, preparation ratio of standard deviations and variances.

UNIT IV TESTING OF HYPOTHESIS AND ANOVA 12

Hypothesis testing – Small samples – Tests concerning proportion, means, standard deviations – Tests based on chi square – and Redistribution test -Design of experiments.

UNIT V ANOVA 12

Design of experiments – One, Two factor Models

TOTAL: 60 PERIODS

OUTCOME

At the end of the course, the student will be

CO1 Able to analyze the performance in terms of probabilities and distributions achieved by the determined solution.

CO2 Aware of various test statistics for the samples.

CO3 Able to develop an ability to apply statistical tests in experiments as well as to analyze and interpret data.

CO4 Able to use the statistical tools for their project and future research.

CO5 Able to use the concepts in design of experiments in real life problems.

REFERENCES

1. Gupta and Kapoor, “Fundamentals of Applied Statistics”, Sultan Chand and sons, 4th Edition, New Delhi, 2019.
2. Hooda, “Statistics for Business and Economics”, Macmillan, 3rd Edition, India, 2003.
3. John.E.Freunds, “Mathematical statistics with applications”, Pearson Education, 8th Edition, New Delhi, 2013.
4. Levin and Rubin, “Statistics for Management”, Pearson Education India, 7th Edition, New Delhi, 2013.

CO-PO Mapping:

	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	2	2
CO2	3	3	3	3	2	2
CO3	3	3	3	3	2	2
CO4	3	3	3	3	2	2
CO5	3	3	3	3	2	2
Avg	3	3	3	3	2	2

RM3151 RESEARCH METHODOLOGY AND IPR L T P C
2 1 0 3

UNIT I RESEARCH PROBLEM FORMULATION 9

Objectives of research, types of research, research process, approaches to research; conducting literature review- information sources, information retrieval, tools for identifying literature, Indexing and abstracting services, Citation indexes, summarizing the review, critical review, identifying research gap, conceptualizing and hypothesizing the research gap

UNIT II RESEARCH DESIGN AND DATA COLLECTION 9

Statistical design of experiments- types and principles; data types & classification; data collection - methods and tools

UNIT III DATA ANALYSIS, INTERPRETATION AND REPORTING 9

Sampling, sampling error, measures of central tendency and variation,; test of hypothesis- concepts; data presentation- types of tables and illustrations; guidelines for writing the abstract, introduction, methodology, results and discussion, conclusion sections of a manuscript; guidelines for wring thesis, research proposal; References – Styles and methods, Citation and listing system of documents; plagiarism, ethical considerations in research

UNIT IV INTELLECTUAL PROPERTY RIGHTS 9

Concept of IPR, types of IPR – Patent, Designs, Trademarks and Trade secrets, Geographical indications, Copy rights, applicability of these IPR; , IPR & biodiversity; IPR development process, role of WIPO and WTO in IPR establishments, common rules of IPR practices, types and features of IPR agreement, functions of UNESCO in IPR maintenance.

UNIT V PATENTS 9

Patents – objectives and benefits of patent, concept, features of patent, inventive steps, specifications, types of patent application; patenting process - patent filling, examination of patent, grant of patent, revocation; equitable assignments; Licenses, licensing of patents; patent agents, registration of patent agents.

TOTAL: 45 PERIODS

REFERENCES:

1. Cooper Donald R, Schindler Pamela S and Sharma JK, “Business Research Methods”, Tata McGraw Hill Education, 11e (2012).
2. Soumitro Banerjee, “Research methodology for natural sciences”, IISc Press, Kolkata, 2022,
3. Catherine J. Holland, “Intellectual property: Patents, Trademarks, Copyrights, Trade Secrets”, Entrepreneur Press, 2007.

4. David Hunt, Long Nguyen, Matthew Rodgers, “Patent searching: tools & techniques”, Wiley, 2007.
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.

BP3101 FORMULATION TECHNOLOGY L T P C
4 0 0 4

OBJECTIVES
The course aims to enable the students to acquire theoretical knowledge on pharmaceutical dosage forms.

UNIT I DESIGN OF DOSAGE FORMS 12
Definitions, Classification and needs of Dosage forms. Routes of dosage administration (Oral, Parenteral, Topical, Rectal and Nasal). Pharmaceutical and Formulation considerations for Dosage form development; preformulation and stability studies -physical form, polymorphism, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic property and chemical properties of drugs - hydrolysis, oxidation, reduction, racemization, polymerization. Biopharmaceutical and Pharmacokinetic considerations for Dosage form development.

UNIT II SOLID DOSAGE FORMS 12
Tablets: Different types of tablets. Excipients used in tablets. Manufacturing and evaluation of tablets. Coating- Types, materials for coating, formulation, equipment’s, film defects and evaluation of coated tablets. Solid oral modified- release dosage forms – Extended-Release and Delayed Release Oral Dosage Forms.
Capsules: Materials for production of hard/Soft gelatin capsules, size of capsules and method of capsule filling. Manufacturing, quality control, stability and storage of capsule dosage forms. Micro-encapsulation - Classification, Methods of preparation and Evaluation of microcapsules.

UNIT III LIQUID, SEMI-SOLID AND AEROSOLS 12
Liquid Dosage forms: Solutions, Emulsion and Suspension - Additives in formulations; vehicles, stabilizers, preservatives, suspending agents, emulsifying agents, solubiliser, colors, flavors etc. Manufacturing, packaging and evaluation of Solutions, Emulsion and Suspension.
Semisolid Dosage Forms: Mechanisms of drug penetration, factors influencing penetration, semisolid bases and their selection. General formulations of semisolids like Cream, Gel, Paste; Suppositories, manufacturing procedure, evaluation and packaging.
Aerosols: Types of propellants, general formulation, manufacturing, packaging methods, pharmaceutical applications and evaluation.

UNIT IV STERILE DOSAGE FORMS 12
Parenterals - Official Types of Injections, Additives -Solvents and Vehicles, Polymeric and Surface Active Compounds, Chelating Agents, Antioxidants, Buffers, Bulking Agents, Protectants, and Tonicity Adjusters. Manufacturing, evaluation and packaging of Parenterals. Formulation of Biopharmaceuticals - microbiological considerations, Excipients - solubility enhancers, anti-adsorption and anti-aggregation agents, buffer components, preservatives and antioxidants, osmotic agents. Shelf Life of Protein-Based Pharmaceuticals. Routes of drug administration of Biologics. Formulation of Insulin, Vaccine, Toxins, Antitoxin, Immunoglobulin.

UNIT V NOVEL DRUG DELIVERY SYSTEMS 12

Delivery of proteins: approaches for rate-controlled and target site-specific delivery by the parenteral route. Nasal; Ophthalmic and Otic Preparations; Packaging biopharmaceutical dosage design & delivery. Novel Drug delivery systems – Transdermal delivery systems, Osmotic drug delivery systems and Nanoparticles.

TOTAL: 60 PERIODS

OUTCOMES:

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

CO1 Define, classify and evaluate various dosage forms
CO2 Formulate and evaluate solid dosage forms
CO3 Formulate and evaluate aerosols, liquid and semisolid dosage forms
CO4 Develop and analyse parenterals and biopharmaceuticals
CO5 Formulate and characterize novel drug delivery systems

REFERENCES

1. Ansel, H.C. "Pharmaceutical Dosage Forms and Drug Delivery Systems", 11th Edition, Lippincott Williams & Wilkins, 2018.
2. Tipnis, H.P. "Bioavailability and Bioequivalence: An Update". New Age International, 1996.
3. Lieberman, H.A. "Pharmaceutical Dosage Forms: Tablets". Vol.1-3, 2ndEdition, Marcel Dekker, 2005.
4. Lieberman, H.A. "Pharmaceutical Dosage Forms: Parenteral Medications", Vol.1-3, 2nd Edition, Marcel Dekker, 2005.
5. Lieberman, H.A. "Pharmaceutical Dosage Forms: Disperse Systems", Vol.1-3, 2nd Edition,Marcel Dekker, 2005.
6. Lippincott, "Remington's The Science and Practice of Pharmacy", Vo.1 & 2, 20th Edition, Williams& Wilkins, 2004.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	2	1	1	2	2	2
CO2	3	2	3	2	3	3
CO3	3	2	3	2	3	3
CO4	3	2	3	2	3	3
CO5	3	2	3	2	3	3
Avg	2.8	1.8	2.6	2	2.8	2.8

BP3151 MOLECULAR PHARMACOLOGY L T P C
3 0 0 3

OBJECTIVE

The course aims to provide knowledge on pharmacology and toxicology of drugs.

UNIT I OVERVIEW OF DRUGS ACTING ON VARIOUS SYSTEMS 9

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

UNIT II RECEPTORS AND THEIR MODE OF ACTION 9

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

UNIT III BIOACTIVE MOLECULES 9

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. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.

UNIT IV MOLECULAR MECHANISM OF DRUG ACTION 9

Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phosphatidylinositol. Ion channels and their modulators.: Basic concepts in molecular pharmacology: agonists, antagonists and inverse agonists; potency, intrinsic activity and efficacy; mechanisms of signaling and its inhibition; measurement of binding and response. Preparation, G protein-coupled receptors, G proteins and effectors, Mechanism of G protein-mediated signaling, hedgehog and notch, Intrinsic tyrosine kinases, Biophysical characterization of ion flux, Voltage-gated ion channels.

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 etc.,

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Name and explain drugs acting on various systems
CO2 Define and classify receptors
CO3 List and describe bioactive molecules
CO4 Classify receptors and explain drug receptor interactions
CO5 Design and carry out toxicity studies as per guidelines

REFERENCES

1. Satoskar, “Pharmacology and Therapeutics”, Elsevier India, 25th edition, 2017.
2. Tripathi, K.D. “Medical Pharmacology”, Jaypee Brothers Medical Publishers, 8th edition, 2018.
3. Karen Whalen, “Lippincott Illustrated Reviews: Pharmacology”, Lippincott Williams and Wilkins, 6th Edition, 2014.
4. Rang, M.P, Dale M.M, Reter J.M, “Pharmacology”, Churchill Livingstone, 8th revised edition, 2015.
5. Laurence Brunton , Bjorn Knollmann , RandaHilal-Dandan, “Goodman and Gilman’s: The Pharmacological basis of therapeutics”, McGraw-Hill Education / Medical, 13th edition, 2017.
6. Kulkarni S.K., “Handbook of Experimental Pharmacology”, 2016
7. Katzung, B.G., “Basic and Clinical Pharmacology”, 13th Edition, McGraw Hill 2015.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	2	1	2	2	3	2
CO2	2	1	1	1	-	2
CO3	2	1	1	1	-	2
CO4	2	1	2	2	3	2
CO5	2	1	2	2	3	2
Avg	2	1	1.6	1.6	3	2

BP3111 FORMULATION TECHNOLOGY LABORATORY L T P C
0 0 4 2

OBJECTIVE

The course aims to provide hands on experience on formulation and evaluation of various dosage forms

LIST OF EXPERIMENTS

1. Preparation of pharmaceutical buffers and determination of buffer capacity, physiological buffers.
2. Preparation of solid dosage forms (Eg. Granules, Tablets, Capsules)
3. Preparation of liquid dosage forms (Eg. True Solutions, mixtures, Elixirs)
4. Preparation of biphasic dosage forms (Eg. Emulsion, Suspension)
5. Preparation of semisolid dosage forms (Eg. Ointments, Creams, Gels, lotions)
6. Preparation of Parenteral and ophthalmic formulations
7. Preparation of Protein formulations.
8. Preparation of specialized dosage forms (Eg. Suppositories, Patches)
9. Evaluation of solid dosage forms (Hardness, dissolution etc)
10. Evaluation of liquid dosage forms (Stability tests, pH, odour etc)
11. Evaluation of biphasic dosage forms (Stability tests etc)
12. Evaluation of semisolid dosage forms (pH, spreadability, viscosity etc)
13. Evaluation of Parenteral formulations (Microbial Tests etc)
14. Evaluation of Protein formulations (Stability tests - Aggregation test)

TOTAL :60 PERIODS

COURSE OUTCOMES:

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

CO1 Prepare and evaluate solid, liquid, semisolid and parenteral formulations
CO2 Calculate shelf life of products
CO3 Gain hands on experience in formulation of dosage forms

REFERENCES

1. Ansel, H.C. “Pharmaceutical Dosage Forms and Drug Delivery Systems”, 7th Edition, Lippincott Williams & Wilkins, 2000.
2. Avis, K.E., “Pharmaceutical Dosage Forms: Parenteral Medications”, (Vol.I, II & III) 2nd Rev. Edition, Marcel Dekker, 1992.
3. Lachman, Leon “The Theory And Practice of Industrial Pharmacy”, 4th Edition, Varghese Publishing House, 2013.
4. Lieberman, H.A.., “Pharmaceutical Dosage Forms: Disperse Systems” (Vol.I, II & III) 2nd Rev. Edition, Marcel Dekker, 1996.
5. Lieberman, H.A. “Pharmaceutical Dosage Forms: Tablets” (Vol. I, II & III) 2nd Edition,

Marcel Dekker, 1989.
6. USP NF, guidelines: http://www.usp.org, https://www.uspnf.com, & http://www.fda.gov.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	2	1	1	2	2	2
CO2	3	2	3	2	3	3
CO3	3	2	3	2	3	3
CO4	3	2	3	2	3	3
CO5	3	2	3	2	3	3
Avg	2.8	1.8	2.6	2	2.8	2.8

SEMESTER II

BP3201 APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS L T P C
3 0 0 3

OBJECTIVE

The course aims to enable the students to understand the importance of biopharmaceutics and pharmacokinetics in developing a stable dosage form and dosage regimen

UNIT I FUNDAMENTALS ON DRUG ABSORPTION AND DISTRIBUTION 9

Definitions, various routes of administration with advantages/disadvantages, bioavailability concepts in drug absorption and distribution, theories of drug dissolution, drug partition hypothesis, permeability and distribution of drugs, perfusion rate and volume of distribution, protein binding of drugs, kinetics of drug binding, various factors that affect drug absorption and distribution, drug interactions in the level of drug absorption and distribution.

UNIT II FUNDAMENTALS ON DRUG METABOLISM AND EXCRETION 9

Biotransformation of drugs, pathways and enzymes of drug metabolism, Phase I and Phase II, drugs excretion –renal and non-renal routes, various factors that affect drug metabolism and excretion, prodrugs, drug interactions in the level of drug metabolism and excretion, bioavailability concepts in drug metabolism and excretion.

UNIT III PHARMACOKINETIC INVESTIGATION AND EVALUATION 9

Concept of therapeutic concentration, time-profile, rates and various order of reactions (first, zero, mixed), Michaelis-Menton kinetics, differential equations for a simple pharmacokinetic models, compartment models (one, two, multi, open models), definition and calculation of parameters such as drug half-life, of Drugs, Volume of Distribution, and bioavailability(AUC) and their application to compartment models and kinetics of IV Bolus administration, comparison between bioavailability and bioequivalence.

UNIT IV PHARMACODYNAMIC FUNDAMENTALS 9

Definitions – agonist/antagonist, antagonism as a mechanism of drug action, classification of antagonists, drug-receptor interactions, factors affecting drug-target interactions, law of mass action applied to drugs, quantifying drug-target interactions: dose-response relationships - graded dose and quantal dose-responses; molecular mechanisms mediating drug action, receptor coupling and transduction mechanisms, intracellular transduction mechanisms, second messenger systems, amplification of drug responses, factors modifying drug responses.

UNIT V PHARMACOKINETICS AND PHARMACODYNAMICS OF BIOPHARMACEUTICALS 9

Pharmacokinetics of Protein Therapeutics – Absorption through Enteral Administration and Parenteral Administration, Distribution Mechanisms and Volumes, Protein Binding, Elimination; Proteolysis, Protein Metabolism - Gastrointestinal, Renal and Hepatic, Receptor-Mediated Protein Metabolism, Target-Mediated Drug Disposition, Chemical Modifications and Pharmacokinetics of Therapeutic Protein

Pharmacodynamics of Protein Therapeutics – PK/PD Models – Direct link PK/PD models, Indirect link PK/PD models, Indirect response PK/PD models, Cell lifespan models, Complex response models

TOTAL:45 PERIODS

OUTCOME

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

CO1 Classify and explain various mechanisms of drug absorption
CO2 Describe various metabolic pathways and excretion processes.
CO3 Calculate various Pharmacokinetic parameters
CO4 Calculate pharmacodynamic parameters and predict drug response
CO5 Apply knowledge of PK/PD and design dosage regimen

REFERENCES

1. Brahmankar, D.M., “Biopharmaceutical and Pharmacokinetics: A Treatise”, VallabhPrakashan, 2015
2. Notari, R.E., “Biopharmaceutics and Clinical Pharmacokinetics: An Introduction”, 4th Edition, Marcel Deckker, 2005.
3. Schoenwald, R.D., “Pharmacokinetics in Drug Discovery and Development”, CRC Press, 2002.
4. Oliver Kayser, Rainer H. Müller, “Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications”, Wiley-VCH publications, 2nd edition, 2012.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	2	1	2	2	2	2
CO2	2	1	2	2	2	2
CO3	3	1	3	2	2	3
CO4	3	1	3	2	2	3
CO5	3	1	3	2	2	3
Avg	2.6	1	2.6	2	2	2.6

BP3202 IMMUNOPHARMACOLOGY L T P C
3 0 0 3

OBJECTIVE

The course aims to provide knowledge on

- Diseases of the human immune system.
- Classification and application of immunotherapeutic drugs, vaccines and biologicals.

UNIT I PHARMACOLOGY OF AGENTS AFFECTING IMMUNE SYSTEM 9

Overview of discovery and development of immuno-drugs.and various therapeutic pathways and targets of immune system, immune cell and organ classification, neuro humoral regulation of immune responses, complement pathways, cytokine classification and activation, T-cell and B-cell development, Principles of basic and clinical pharmacokinetics

and pharmacodynamics of immune drugs; bioassay and animal models for immune drug validation.

UNIT II VACCINOLOGY AND IMMUNODIAGNOSTICS 9

T and B epitopes classification, adjuvant and hapten classification, immuno-screening of antigens, vaccine formulation technology, vaccine production and validation, recombinant vaccines, peptide vaccines, reverse vaccinology, therapeutic vaccines. Monoclonal antibody production and application, antibody engineering, scFv Antibodies, immunoconjugates, immunotoxins. Immunodiagnostics – ELISA types, principle/development of Rapid immuno diagnostic tests.

UNIT III IMMUNO THERAPEUTICS AND IMMUNE CANCER THERAPEUTICS 9

(WHO) Anatomical Therapeutic Chemical (ATC) Classification of drugs affecting the immune system (L, L01, L02, L03, L04), therapeutic use of cytokines, classification – immunostimulators; immunomodulators, therapeutic Mabs classification and formulation.Cancer vaccines, CAR T-cell therapy, immune check-point inhibitors.

UNIT IV TRANSPLANTATION 9

Laws of transplantation, host vs graft and graft versus host reactions; HLA Classification, drugs for immunosuppressive therapy: corticosteroids, Antimetabolites and calcineurin inhibitors, immunosuppressive drugs and adjuvant therapies.

UNIT V IMMUNOLOGY OF ALLERGY 9

Classification of hypersensitivity reactions, Classification of allergens, Adverse drug reactions, Drug Hypersensitivity – pharmacologic perspective, immunologic perspective, Off-target toxicity, Cellular Basis, Chemical Basis – The Hapten/pro hapten hypothesis, The Danger theory, The pi concept, therapy and prevention of allergies;. Pharmacology of antihistamines, classification, histamine stabilizers, anti-inflammatory agents, anti-rheumatoid drugs, Disease-modifying antirheumatic drugs (DMARDs).

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Explain the pharmacology of drugs affecting the immune system.
CO2 Develop and evaluate immunotherapeutics for emerging diseases.
CO3 Classify immunostimulators and immunomodulators
CO4 Describe about immunosuppressant therapy
CO5 Classify allergens and explain about the treatment of allergies

REFERENCES

1. Janeway, C.A., Travers, P., Walport, M. &Shlomchk, M.J. “Immunobiology”, 6th Edition, Churchill, Livingstone, 2005.
2. Male, D., Brostoff, J., Roth, D. &Roitt, I. “Immunology”, 7thEdition, Elsevier, 2006.
3. Mycek M.J., Garnet S.B and Perper M.M. “Lippincott’s Illustrated Pharmacology Reviews”, Lippincott Company, Philadelphia, 6th Edition, 2014.
4. Goodman and Gilman’s, The Pharmacological basis of therapeutics, McGraw-Hill Education / Medical; 13th edition, 2017.

Course Articulation Matrix

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

CO4	2	3	2	2	1	1
CO5	2	2	3	2	1	1
Avg	2	2.4	2.4	2	1	1

BT3252 ANIMAL CELL CULTURE TECHNOLOGY L T P C
3 0 0 3

OBJECTIVES

- The course aims to provide advanced knowledge on the principles of utilizing recombinant cells/ transgenic animals for clinical/industrial applications

UNIT I INTRODUCTION 9

Scope of Animal Biotechnology, Animal Biotechnology for production of regulatory proteins, blood products, vaccines, hormones and other therapeutic proteins.

UNIT II VIRAL EXPRESSION SYSTEM 9

Biology of animal viral vectors- SV40, adenovirus, retrovirus, vaccinia virus, herpes virus, adeno associated virus and baculovirus.

UNIT III CELL CULTURE TECHNOLOGY 9

Culturing of cells, primary and secondary cell lines, Cell culture-Scaling up of animal cell culture- monolayer culture, suspension culture; Various bioreactors used for animal cell culture-Roller bottle culture; Bioreactor process control, stirred animal cell culture, Air-lift fermentor, Chemostat/Turbidostat; High technology vaccines: Hybridoma technology; Cell lines and their applications

UNIT IV GENETIC ENGINEERING 9

Gene therapy-prospects and problems; Knockout mice and mice model for human genetic disorder; Baculovirus in biocontrol; Enzymes technology, Somatic manipulation of DNA, Nucleic acid hybridization and probes in diagnosis- preparation of probes, evaluation and applications.

UNIT V APPLICATIONS 9

Rumen manipulation- probiotics embryo transfer technology, in vitro fertilization, transgenesis- methods of transferring genes into animal oocytes, eggs, embryos and specific tissues by physical, chemical and biological methods; Biopharming - Transgenic animals (Mice, Cows, Pigs, Sheep, Goat, Birds and Insects); Artificial insemination and embryo transfer, cryopreservation and CRISPR.

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Acquire knowledge on animal biotechnology.
CO2 Use molecular biology tools for viral vector based gene delivery.
CO3 Understand scaling up cell culture in industry.
CO4 Describe the importance of genetic engineering in animal biotechnology.
CO5 Apply animal biotechnology knowledge in livestock industry.

REFERENCES

1. Watson, J.D., Gilman, M., WitowskiJ.and Zoller, M. “Recombinant DNA”, W. H. Freeman, 3rd edition, 2007.
2. Glick, B.R. and Pasternack, J.J. “Molecular Biotechnology”, 3rd edition, ASM Press, 2003.

3. Lewin, B. “Genes VIII”, Pearson Prentice Hall, 2004.
4. Davis J.M. “Basic Cell Culture: A Practical Approach”, IRL Press, 2002.
5. Freshney R.I. “Animal Cell Culture- a practical approach”, 1987.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	3	3	2	-	2	-
CO2	-	3	3	-	2	3
CO3	3	3	2	1	-	3
CO4	3	3	3	-	3	1
CO5	-	3	-	3	3	3
Avg	3	3	2.5	2	2.5	2.5

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BP3203 REGULATORY AFFAIRS IN THE PHARMACEUTICAL INDUSTRY L T P C
3 0 0 3

OBJECTIVES

The course aims to provide knowledge on

- Drug regulatory affairs in India and at International level.
- Intellectual property rights, drug development approval processes and safety management.

UNIT I INTRODUCTION TO DRUG REGULATORY LAWS 9

Drugs and Cosmetics Act 1940 and its rules 1945 National Pharmaceutical Pricing Authority (NPPA), The Environmental Protection Act-1986&Occupational Safety and Health Administration (OSHA), Consumer Protection Act-1986, Factories Act-1948 and Pollution control Act-1989, The Drugs (Prices Controls) Order, 1955. The Indian Patents and Designs, Act 1970, Magic Remedies and Objectionable advertisements Act, Prevention of Food Adulteration Act 1954.Intellectual Property Rights, ICH guidelines for clinical trials, therapeutic drug monitoring and bioequivalence. Exclusive marketing rights.

UNIT II PHARMACOPOEIA 9

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

UNIT III cGMPS & REGULATORY RECORDS 9

cGMP concepts – Development, Manufacturing Record, Analytical &process Validation, Equipment & utility Qualification and Calibration, Personnel procedures; Regulatory bodies & requirements - Indian FDA, WHO GMP; U.S. FDA, U.K. MCA, Australian TGA, Japanese PMDA. Drug dossier contents - CTD (CMC section) & data.

UNIT IV DRUG DEVELOPMENT APPROVAL PROCESS/CLINICAL TRIALS 9

Drug development stages, FDA guidelines on IND, new drug approvals (NDA), ANDA approvals. European regulatory agency, types of filing process (Centralized, decentralized, RMS countries), Regulation of preclinical studies, Design of clinical studies CFR / ICH / EU GCP guidelines; Schedule-Y, pre-clinical study requirements, clinical trial phases, types of trials, bioethics and stakeholders, Bioavailability & Bioequivalence studies.

UNIT V PRODUCT MANAGEMENT AND QUALITY ASSURANCE 9

GLP, ISO 9000, TQM, Quality Review and Quality Documentation, Regulatory control, regulatory drug analysis, interpretation of analytical data. Basic requirements - design of product, facility, equipment selection and personnel. Industrial hazards due to fire, accident, mechanical, electrical equipment, monitoring and preventive system (Safety measures

including insurance). Effluent testing, treatment and waste management. Safety and Environmental Control. Biosafety Guidelines

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Summarize regulatory laws

CO2 Carry Out drug testing according to pharmacopoeial specifications

CO3 Explain about current regulatory process in the pharmaceutical industry.

CO4 Design clinical trial protocol

CO5 Describe quality standards in pharmaceutical industry.

REFERENCES

1. Abraham, John and Smith, H.W. “Regulation of the Pharmaceutical Industry”, Palgrave, Macmillan, 2003.
2. Weinberg, Sandy “Good Laboratory Practice Regulations” 4th Edition, Marcel Dekker, 2007.
3. Gad, Shayne C. “Drug Safety Evaluation”, Wiley-Interscience, 3rd Edition, 2016.
4. Malik, Vijay “Drugs and Cosmetics Act, 1940”. EBC Publishing Co, 2018.
5. “Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials”, Vol. I & II, World Health Organization and Pharma Syndicate, 2002.
6. Berry, Ira R. and Harpaz, Daniel “Validation of Active Pharmaceutical Ingredients”, 2nd Edition, CRC Press, 2001.
7. British Pharmacopoeia, 2017.
8. United States Pharmacopoeia,2019

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	1	2	1	3	3	2
CO2	2	1	1	2	3	1
CO3	1	2	1	1	2	2
CO4	2	2	3	1	1	-
CO5	1	1	2	2	3	2
Avg	1.4	1.6	1.6	1.8	2.4	1.75

BP3211 IMMUNOPHARMACOLOGY LABORATORY **L TP C**
0 0 6 3

OBJECTIVE

The course aims to provide

- Hands-on-experience on various immunological techniques like ELISA and Flow cytometry
- Practical experience on immunoassays.

LIST OF EXPERIMENTS

1.Selection and Handling of animals used in immunopharmacological assays (Eg. Mice, Rat, Rabbit, Zebra fish, Caenorhabditis elegans etc.,).

2. Preparation of antigens and immunization procedures for raising anti-sera.

3. Demonstration of various methods of bleeding, serum separation and storage.

4. Antibody titre by ELISA method (Indirect ELISA).

5. Sandwich ELISA – Quantification of antigens.

6. Immunoprecipitation/Immunoelectrophoresis.
7. Isolation and purification of IgG from serum or IgY from Egg (Ammonium sulphate method/Protein A, PEG method).
8. Studies for characterisation of antigens - SDS -PAGE, Immunoblotting, Dot blot assays.
9. Assay for immunostimulants (Erythropoietin assay etc.,).
10. Direct Agglutination – Widal test, Salmonella detection.
11. Separation of mononuclear cells by Ficoll-Hypaque.
12. Separation and culturing of splenocytes and demonstration of T cell proliferation.
13. PBMC proliferation/cell viability by mitogen/antigen by MTT or Thymidine uptake assay.
14. Flow Cytometry – Identification of lymphocytes and their subsets.
15. Evaluation of monoclonal antibodies for diagnostic and therapeutic applications.
16. Demonstration of Immunodiagnostics using commercial kits (Rapid Flow through and Lateral flow devices – Dot Blot and StripTest).

TOTAL :90 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to
CO1 understand the importance of immunoassays
CO2 evaluate vaccines and immunotherapeutics.
CO3 apply immunological techniques in academic research.

REFERENCES

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

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	2	2	3	3	2	1
CO2	3	2	3	3	2	1
CO3	2	2	3	2	1	3
Avg	2.3	2.0	3.0	2.6	1.6	1.6

SEMESTER III

BT3261 ANIMAL CELL CULTURE TECHNOLOGY LABORATORY L T P C
0 0 6 3

OBJECTIVES

The course aims to provide knowledge on preservation and propagation of animal cell lines

LIST OF EXPERIMENTS

1. Preparation of media and sterilization techniques for animal cell culture.
2. Preparation of primary cell culture.
3. Preparation of continuous Cell lines (Eg. CHO, cancer cell lines, SP2O, etc).
4. Staining of Animal Cells and Cell Counting. 5. Viability of animal cells by MTT assay.
6. Various methods of cell perseveration and propagation.

7. Transfection of animal cell vectors (Eg. pBUD, pVAXetc) in mammalian expression system.
8. Cultivation of recombinant CHO cell lines in bioreactor.
9. Cell separation from medium by centrifugation, filtration.
10. Purification and concentration of recombinant proteins by ammonium sulphate / aqueous two- Phase methods.
11. Evaluation of post-translational modification by SDS-PAGE-Schiff staining and other methods.
12. Demonstration of hybridoma fusion and propagation.
13. Cultivation of monoclonal antibodies in bioreactor.
14. Expression and purification of prototype therapeutic proteins insect cell lines.
15. Culture of virus in chick embryo.

TOTAL :90 PERIODS

COURSE OUTCOMES:

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

CO1 Perform cell culture techniques

CO2 Handle animals and perform recombinant gene techniques

CO3 Design and perform experiments on recombinant proteins and monoclonal antibodies production

REFERENCES

1. Animal Cell Culture and Technology, The Basics, Garland Science, 2nd Edition, Taylor and Francis, 2004.
2. Freshney, Culture of Animal Cells, 5th Edition, Wiley-Liss, 2005.
3. John R.W. Masters, Animal Cell Culture - Practical Approach, 3rd Edition, Oxford
1. University Press, 2000.
4. Ed. Martin Clynes, Animal Cell Culture Techniques., Springer, 1998.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	2	-	1	2	3	3
CO2	3	-	2	2	3	3
CO3	2	-	2	2	3	3
Avg	2.3	-	1.6	2	3	3

BT3361 SOPHISTICATED ANALYTICAL TECHNIQUES LABORATORY L T P C
0 0 6 3

OBJECTIVES

The course aims to acquaint students with skills needed for understanding the theory, operation and applications of sophisticated analytical laboratory instruments

LIST OF EXPERIMENTS

1. Estimation of DNA/protein concentration by conventional and NanoDrop methods.
2. Preparative and qualitative estimation of biomolecules by HPLC analysis.
3. Evaluation of proteins by SDS-PAGE and Western blot (Chemiluminescence Fluorescence detection methods).
4. Evaluation of proteins by 2D Gel electrophoresis (demo).
5. Protein mass determination by MALDI-TOF analysis- demo.
6. Determination of pathogens by Mass spectrometry.

7. Analysis by Real-time PCR (SYBR green method) with melting curve analysis.
8. Determination of protein aggregation by Dynamic Light Scattering (DLS).
9. Evaluation of cells by Confocal microscopy.
10. FTIR analysis of biomolecules.
11. GC-MS on small molecule analysis- demo.
12. Flow cytometry analysis of cell cycle- demo.

TOTAL: 90 PERIODS

OUTCOMES

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

CO1 Summarize basic and widely used techniques in the analysis of biomolecules.

CO2 Demonstrate overall techniques associated with proteomics such as protein separation by 2D-gel and characterization using mass spectrometer.

CO3 Experiment with fluorescence based real-time PCR, cell/tissue confocal imaging and separation using flow cytometer.

REFERENCES

1. Skoog, D.A., West, D.M., and Holler, F. “Fundamentals of Analytical Chemistry”, 7th Edition. Brooks Cole, 2015.
2. Primrose S.B., Twyman R.H., and Old R.W. “Principles of Gene Manipulation”, 6 th Edition., Blackwell Science, 2001.
3. Chapman J. R. “Mass Spectrometry of Proteins and Peptides” (Methods in Molecular Biology – Vol 146) Humana Press. 2000.
4. Simpson R. J. “Proteins and Proteomics - A Laboratory Manual”, Cold Spring Harbour Laboratory Press, 2002.
5. Rosenberg I. M. “Protein analysis and Purification – Benchtop Techniques”, Springer, 2005.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	3	3	2	3	3	2
CO2	3	3	2	3	3	2
CO3	2	3	3	2	2	3
Avg	2.6	3	2.3	2.6	2.6	2.3

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BP3311 COMPUTATIONAL METHODS IN DRUG DISCOVERY LABORATORY LT P C
1 0 4 3

OBJECTIVES

The course aims to make students to

● Understand pharma 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 Pharmacophore identification.
9. Drug like property evaluation of compounds and ADME (Lipinski's rule of five).
10. Molecular docking : Protein – Protein, Protein-Small Molecule.
11. Molecular Dynamics Simulation using GROMACS.
12. Pharmacogenomics : Effect of SNPs / mutations on drug binding using docking approaches.

TOTAL: 90 PERIODS

OUTCOME

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

CO1 Retrieve data related to small molecules, drugs and their targets, use computational tools for their analysis.

CO2 Perform basic next generation sequencing data analysis.

CO3 Perform computational structural studies like QSAR, Molecular docking, Molecular Dynamics simulations and interpret the 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 EijaKorpelainen, JarnoTuimala, PanuSomervuo, Mikael Huss and Garry Wong. CRC Press 2014
7. Next Generation Sequencing Data Analysis, by Xinkun Wang CRC Press.2016

Course Articulation Matrix

Course	Programme Outcome (PO)					
Outcome	**1**	**2**	**3**	**4**	**5**	**6**
CO1	3	1	2	3	1	1
CO2	3	2	3	2	2	1
CO3	3	3	3	2	2	1
Avg	3	2	2.6	2.3	1.6	1

BP3312 **PROJECT WORK I** **L T P C**
0 0 12 6

OBJECTIVES:

The course aims to enable the students to identify the research problem relevant to their field of interest, search databases to define the problem, design experiment, conduct preliminary study and report the findings.

COURSE CONTENT

Individual students will identify a research problem relevant to his/her field of study with the approval of project review committee. The student will collect, and analyze the literature and design the experiment. The student will carry out preliminary study, collect data, interpret the result, prepare the project report and present before the committee.

TOTAL: 180 PERIODS

OUTCOMES:

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

CO1: Identify the research problem

CO2: Collect, analyze the relevant literature and finalize the research problem

CO3: Design the experiment, conduct preliminary experiment, analyse the data and conclude

CO4: Prepare project report and present

Course Articulation Matrix

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

SEMESTER IV

BP3411 **PROJECT WORK II** **L T P C**

0 0 24 12

I. Continuation of Project Work I (at Institution/Industry)

OBJECTIVES:

The course aims to enable the students to conduct experiment as per the plan submitted in Project work I to find solution for the research problem identified.

COURSE CONTENT

The student shall continue Project work I as per the formulated methodology and findings of preliminary study. The student shall conduct experiment, collect data, interpret the result and provide solution for the identified research problem. The student shall prepare the project report and present before the committee.

TOTAL: 360 PERIODS

OUTCOMES:

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

CO1: Conduct the experiment and collect data

CO2: Analyze the data, interpret the results and conclude

CO3: Prepare project report and present

Course articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	3	2	3	3	2	3
CO2	3	3	3	3	2	3
CO3	3	3	3	3	2	3
Avg	3	2.67	3	3	2	3

II. Not the continuation of Project Work I (at Industry)

OBJECTIVES:
The course aims to enable the students to identify the research problem at the company, search databases to define the problem, design experiment, and conduct experiment to find the solution.

COURSE CONTENT
Individual students will identify a research problem relevant to his/her field of study at the company and get approval of project review committee. The student will collect, and analyze the literature and design the experiment. The student will carry out the experiment, collect data, interpret the result, prepare the project report and present before the committee.

TOTAL: 360 PERIODS

OUTCOMES:
At the end of the course the students will be able to
CO1: Identify the research problem
CO2: Collect, analyze the relevant literature and finalize the research problem
CO3: Design and conduct the experiment, analyse the data and conclude
CO4: Prepare project report and present

Course Articulation Matrix

Course	Programme Outcome (PO)					
Outcome	1	2	3	4	5	6
CO1	3	1	3	3	2	3
CO2	3	3	3	3	2	3
CO3	3	1	3	3	2	3
CO4	3	3	3	3	2	3
Avg	3	2	3	3	2	3

BP3054 BIOGENERICS AND BIOPHARMACEUTICALS L T P C
3 0 0 3

OBJECTIVE
The course aims to introduce the students about manufacturing processes and characterisation of biosimilars.

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 9

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.,

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Acquire knowledge about basic concepts of biogenerics and biosimilars
CO2 List the industries dealing with biosimilars and its market value
CO3 Carry out various analytical methods for the characterisation of biosimilars.
CO4 Understand the factors contributing immunogenicity to biopharmaceuticals
CO5 Summarise the biopharmaceutical concepts using case studies

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 TransformingProteins and Genes into Drugs”, 2nd edition, 2013
3. “Biopharmaceuticals: Biochemistry and Biotechnology” by Gary Wash , 2 nd edition, 2013
4. Sarfaraz K.Niazi “Biosimilars and Biologics:Implementation and Management” , First edition, 2017
5. Shayne Cox Gad “Handbook of Pharamaceutical Biotechnology” ,First edition,2007

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	2	3	2	-	-	2
CO2	-	3	2	-	2	2
CO3	2	3	2	3	-	3
CO4	-	3	3	-	-	-
CO5	-	-	3	3	-	-
Avg	2	3	2.4	3	2	2.33

BT3052 ENVIRONMENTAL BIOTECHNOLOGY L T P C
3 0 0 3

OBJECTIVE

- The course aims to
- teach students the scientific and technological principles to treat and minimize global environmental problems.
- Provide knowledge on sustainable technologies with modern biotechnological principles.

UNIT I FUNDAMENTAL OF ENVIRONMENTAL BIOTECHNOLOGY 9

Microbial flora of soil, Ecological adaptations, Interactions among soil microorganisms, biogeochemical role of soil microorganisms. Biodegradation, Microbiology of degradation and its mechanism, Bioaugmentation, Biosorption, Bioleaching, Bioremediation- Types of Bioremediation, Bioreactors for Bioremediation, Metabolic pathways for Biodegradation for specific organic pollutants.

UNIT II POLLUTION AND CONTROL 9

Pollution- Sources of pollutants for Air, Water (ground water, marine), Noise, Land and its characteristics- Pollution control and management- Environmental monitoring & sampling, Physical, chemical and biological methods and analysis- Air pollution- control and treatment strategies. Modes of Biological treatment methods for waste water aerobic digestion, anaerobic digestion, Anoxic digestion, the activated sludge process, Design and modeling of activated sludge processes, Aerobic digestion, Design of a trickling biological filter, Design of anaerobic digester.

UNIT III INDUSTRIAL WASTE MANAGEMENT 9

Industrial waste management- Dairy, Paper and Pulp, Textile, leather, hospital and pharmaceutical industrial waste management, e-waste- radioactive and nuclear power waste management- Solid waste management.

UNIT IV MODERN TOOLS OF BIOREMEDIATION 9

Molecular biology tools for Environmental management, rDNA technology in waste treatment, Genetically modified organisms in Waste management, Genetic Sensors, Metagenomics, Bioprospecting, Nanoscience in Environmental management, Phytoremediation for heavy metal pollution, Biosensors development to monitor pollution.

UNIT V RENEWABLE ENERGY SOURCES AND ENERGY MANAGEMENT 9

Alternate Source of Energy, Biomass as a source of energy, Biocomposting, Vermiculture, Biofertilizers, Organic farming, Biofuels, Biomineralization, Bioethanol and Biohydrogen, Bio-electricity through microbial fuel cell, energy management and safety

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Explain the types of bioremediation
CO2 Classify pollutants and explain about pollution control methods
CO3 Explain about waste management
CO4 Develop biosensors to monitor pollution
CO5 Elaborate on management of renewable energy sources

REFERENCES

1. Bruce E. Rittmann and Perry L Mc Carty,"Environmental Biotechnology", (2nd Ed) 2020, Mc Graw Hill Publ.
2. Young-Cheol Chang, "Microbial biodegradation of xenobiotic compounds",Taylor and Francis Ltd. 2021

3. Franklin Burton and H. David Stensel, “Wastewater Engineering: Treatment and Reuse by George Tchobanoglous”, McGraw Hill Publ., 2017
4. Shree Nath Singh (Ed), “Microbial degradation of Xenobiotics”, Springer Publ., Heidelberg, 2012.
5. Garima Kaushik, “Applied Environmental Biotechnology: Present Scenario and Future Trends” Springer Publ., New Delhi (2015).
6. J. Sangeetha, D. Thangadurai, M. David and M. A. Abdullah, “Environmental Biotechnology: Biodegradation, Bioremediation and Bioconversion of xenobiotics for Sustainable Development”, Apple Academic Press Inc., Canada, 2017.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	-	3	2	2	-	1
CO2	2	3	2	1	1	2
CO3	-	3	-	2	-	-
CO4	2	3	2	2	2	2
CO5	-	3	-	-	-	-
Avg	2	3	2	1.75	1.5	1.66

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BT3053 ENZYME ENGINEERING AND TECHNOLOGY L T P C
3 0 0 3

OBJECTIVE

The course aims to provide knowledge on enzyme kinetics and immobilisation techniques.

UNIT I ENZYMES, COENZYMES AND COFACTORS 9

Enzymes: Enzyme as biological catalysts; activation energy, specificity, Enzyme action, active site, enzyme substrate complex, cofactors, Classification, Source of enzymes; production, isolation and purification of enzymes; Characterization in terms of pH, temperature, ionic strength, substrate and product tolerance, effects of metal ions; Coenzymes and cofactors: Coenzymes, classification of vitamins, role and mechanism of action of some important coenzyme (NAD+/NADP+, FAD, lipoic acid, tetrahydrofolate,B12-coenzyme), role of cofactors with specific examples.

UNIT II ENZYME KINETICS 9

Methods for investigating the kinetics of Enzyme catalysed reactions – order of reaction, initial velocity studies. Michaelis-Menten equation, Km and Vmax, enzyme inhibition; methods of plotting enzyme kinetics data; Enzyme turnover number, Solution of numerical problems. competitive, non- competitive, uncompetitive, irreversible; order of reaction,methods of plotting enzyme kinetics data; determination of Kcat, Km, Vmax, Ki, Half Life, effect of pH and Temperature on enzyme activity Multi Substrate enzymes and kinetics mechanisms; Enzyme induction, repression, covalent modification, Isoenzymes, allosteric effects.

UNIT III ENZYME ENGINEERING 9

Introduction, Random and rational approach of protein engineering; Directed evolution and its application in Biocatalysis; various approaches of creating variant enzyme molecules; Future of Biocatalysis; Ideal biocatalyst.

UNIT IV IMMOBILIZED ENZYME TECHNOLOGY 9

Different techniques of immobilization of enzymes and whole cells; Advantages and disadvantages of immobilization; Cross linked enzymes, enzyme crystals, their use and preparation Kinetics of immobilized enzymes, design and operation of immobilized enzymes

reactors; Type of reactors, classification, retention of enzymes in a reactor, kinetics of enzyme reactors; Reactor performance with inhibition, operation of enzyme reactors; case studies; Application and future of immobilized enzyme technology

UNIT V ENZYMATIC TRANSFORMATION 9

Functional group interconversion using enzymes (hydrolysis reaction, oxidation/reduction reactions, C-C bond formations). Reaction engineering for enzyme-catalyzed biotransformations.Catalytic antibodies.Biocatalysts from extreme Thermophilic and Hyperthermophilic microorganisms (extremozymes). The design and construction of novel enzymes, artificial enzymes, Biotransformation of drugs (hydroxylation of Steroids), Host Guest Complexation chemistry, enzyme design using steroid templates, enzymes for production of drugs, fine chemicals and chiral intermediates.

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Classify enzymes and describe about enzyme production and purification processes
CO2 Elaborate on enzyme kinetics and explain about enzyme induction and inhibition
CO3 Describe the importance of biocatalysis.
CO4 Explain the various applications of enzymes
CO5 Summarise enzyme catalysed biotransformations.

REFERENCES

1. Stryer, L. (2002). Biochemistry. Freeman. New York.
2. Lehninger, A. L. (2004). Principles of Biochemistry (4th ed.). Worth. New York, NY.
3. Voet, D., &Voet, J. G. (2004). Biochemistry (4th ed.). Wiley & Sons. Hoboken, NJ: J
4. Rehm, H. & J. Reed, G., (1986). Enzyme Technology. Volume 7a. John Wiley & Sons.
5. Irwin H. Segel, (1976). Biochemical Calculations: How to Solve Mathematical Problems in General Biochemistry, 2nd revised Ed. John Wiley & Sons.
6. Wang, D. I. C. (1979). Fermentation and Enzyme Technology.Wiley. New York.
7. Trevor Palmer , Enzymes IIndHorwood Publishing Ltd. 2007
8. Faber K ,Biotransformations in Organic Chemistry, IV edition , Springer, 2018.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	-	3	2	2	-	1
CO2	2	3	2	1	1	2
CO3	-	3	-	2	-	-
CO4	2	3	2	2	2	2
CO5	-	3	-	-	-	-
Avg	2	3	2	1.75	1.5	1.66

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BT3057 NANO BIOTECHNOLOGY L T P C
3 0 0 3

OBJECTIVE

The course aims to enable the students to learn the basic concepts related to nanotechnology and develop novel drug delivery systems

UNIT I NANOSCALE AND NANOBIOTECHNOLOGY 9

Introduction to Nanoscience and Nanotechnology; Milestones in Nanotechnology; Overview of Nanobiotechnology and Nanoscale processes; Physicochemical properties of materials in Nanoscales.

UNIT II FABRICATION AND CHARACTERIZATION OF NANOMATERIALS 9

Types of Nanomaterials (Quantum dots, Nanoparticles, Nanocrystals, Dendrimers, Buckyballs, Nanotubes); Gas, liquid, and solid –phase synthesis of nanomaterials; Lithography techniques (Photolithography, Dip-pen and Electron beam lithography); Thin film deposition; Electrospinning. Bio-synthesis of nanomaterials.

UNIT III PROPERTIES AND MEASUREMENT OF NANOMATERIALS 9

Optical Properties: Absorption, Fluorescence, and Resonance; Methods for the measurement of nanomaterials; Microscopy measurements: SEM, TEM, AFM and STM. Confocal and TIRF imaging.

UNIT IV NANOBIOLOGY AND BIOCONJUGATION OF NANOMATERIALS 9

Properties of DNA and motor proteins; Lessons from nature on making nanodevices; Reactive groups on biomolecules (DNA & Proteins); Surface modification and conjugation to nanomaterials. Fabrication and application of DNA nanowires; Nano fluidics to solve biological problems.

UNIT V NANO DRUG DELIVERY AND NANOMEDICINE 9

Properties of nano carriers; drug delivery systems used in nanomedicine; Enhanced Permeability and Retention effect; Blood-brain barrier; Active and passive targeting of diseased cells; Health and environmental impacts of nanotechnology.

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Elaborate on fundamental concepts of nanotechnology and nanomaterials
CO2 Classify nanomaterials and explain the synthesis of nanomaterials
CO3 Identify the methods for characterization of nanomaterials
CO4 Describe about the properties and fabrication of nanodevices
CO5 Evaluate nanocarriers for permeability and targeting of diseased cells

REFERENCES

1. Nanobiotechnology: Concepts, Applications and Perspectives, Christ of M. Niemeyer (Editor), Chad A. Mirkin (Editor) , Wiley-VCH; 1 edition, 2004.
2. Nano Biotechnology: Bio-Inspired Devices and Materials of the Future by Oded Shoseyovand Ilan Levy, Humana Press; 1 edition 2007.
3. NanoBiotechnology Protocols (Methods in Molecular Biology) by Sandra J Rosenthal and David W.W right , Humana Press; 1 edition, 2005.
4. Bio-Nanotechnology Concepts and applications. Madhuri Sharon, Maheshwar Sharon,Sunil Pandey and Goldie Oza, Ane Books Pvt Ltd, 1 edition 2012
5. Microscopy Techniques for Material Science. A. R. Clarke and C. N. Eberhardt (Editors)CRC Press. 1st Edition, 2002.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	3	3	-	-	-	-
CO2	-	3	-	1	2	2
CO3	2	3	3	3	3	3
CO4	-	3	3	3	2	3
CO5	-	-	3	-	-	3
Avg	2.5	3	3	2.33	2.33	2.75

BT3056 MOLECULAR PATHOGENESIS OF INFECTIOUS DISEASES LT P C
3 0 0 3

OBJECTIVE

The course aims to impart knowledge on molecular mechanism of various pathogens.

UNIT I INTRODUCTION 9

Discovery of microscope Molecular Koch's postulates, concepts of disease, Virulence, Pathogenic cycle, Vaccines and its historical perspective, Biofilms, quorum sensing, multidrug resistance.

UNIT II HOST DEFENSE AGAINST PATHOGENS AND BACTERIAL DEFENSE STRATEGIES 9

Skin, mucosa, cilia secretions, physical movements, physical and chemical barriers to bacterial colonization, Mechanism of killing by humoral and cellular defenses, Complement, Inflammatory process, Phagocytosis, Colonization, Adherence, Iron acquisition mechanisms, Bacterial defense strategies.

UNIT III MOLECULAR MECHANISMS OF VIRULENCE 9

Virulence, Colonization factors, Microbial toxins, Secretion systems: General secretory pathway, Two-step secretion, Contact dependent secretion, Conjugal transfer system and Auto transporters.

UNIT IV MECHANISMS UNDERLYING MOLECULAR PATHOGENESIS (COMMON ENTERIC PATHOGENS) 9

Shigella: Entry, Induction of macropinocytosis, Invasion of epithelial cells, Intracellular Motility and spread, Apoptotic killing of macrophages, Virulence factors involved. E. coli: Enterotoxigenic E. coli (ETEC), labile & stable toxins, Entero-pathogenic E. coli (EPEC), type III secretion, Cytoskeletal changes, intimate attachment; Enterohemorrhagic. Coli (EHEC), Mechanism of bloody Diarrhea and Hemolytic Uremic Syndrome, Enteroaggregative E. coli(EAEC). Vibrio Cholerae: Cholera toxin, Co-regulated pili, filamentous phage, survival.

UNIT V MECHANISMS UNDERLYING MOLECULAR PATHOGENESIS (COMMON NON-ENTERIC PATHOGENS) 9

Mycobacterium tuberculosis: The Mycobacterial cell envelope, Route of entry, Uptake by Macrophages, Latency and persistence, Entry into and survival in phagocytes, Immune Response against MTB, MTB virulence factors, Emergence of resistance. Influenza Virus: Intracellular stages, Neuraminidase and Haemagglutinin in entry, M1 & M2 protein in assembly and disassembly, action of amantadine. Plasmodium: Life Cycle, erythrocyte stages, transport mechanism and processes to support the rapidly growing schizont, parastiparous vacuoles and knob protein transport, Antimalarial based on transport processes.

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Summarize the various interactions of host and the pathogens.

CO2 Explain the numerous evasion strategies of pathogen against host defence.

CO3 Illustrate about the preventive measures and predictable treatment strategies for infectious diseases.

CO4 List the different pathogens related to infectious diseases

CO5 Describe the pathogens approach on host health cycle.

REFERENCES

1. William Coleman, Gregory Tsongalis, Molecular Pathology "The Molecular Basis of Human Disease", 2nd edition, Nov 1, 2017.

2. Madigan, Michael T. “Biology of Microorganisms”, 13th edition, 2010.
3. Waksman, Gabriel and Michael caparon “Structural Biology of Bacterial Pathogenesis”. American Society for Microbiology, 1st edition, 2005.
4. Salyers, Abigail A. “Bacterial Pathogenesis: A Molecular Approach” American Society for Microbiology; 2nd Revised edition, 2002.
5. Stanley, “Genetic analysis of Pathogenic Bacteria”, 2002.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	3	3	-	-	-	-
CO2	3	3	-	2	-	1
CO3	3	3	-	1	1	-
CO4	3	-	1	1	2	2
CO5	3	-	1	1	2	2
Avg	3	3	1	1.25	1.66	1.66

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BT3058 PLANT DESIGN AND PRACTICE L T P C
3 0 0 3

OBJECTIVE
The course aims to provide knowledge on plant design and GMP guidelines

UNIT I PLANT DESIGN 9
Fermentor design, vessels for Biotechnology, piping and valves for biotechnology, Pressure relief system. Materials of construction and properties. Utilities for plant and their design introduction

UNIT II PROCESS ECONOMICS 9
General fermentation process economics, materials usage and cost, capital investment estimate, production cost estimate. Two case studies – one traditional product and one recombinant product.

UNIT III PHARMACEUTICAL WATER SYSTEM 9
Grades of water, sanitary design, water treatment system, Water distribution system, validation.

UNIT IV VALIDATION OF BIOPHARMACEUTICAL FACILITIES 9
Introduction, why validation, when does validation occur, validation structure, resources for validation, validation of systems and processes including SIP and CIP

UNIT V GOOD MANUFACTURING PRACTICES 9
Structure – quality management, personnel, premises and equipment, documentation, production, quality control, contract manufacturing and analysis, complaints and product recall, self-inspection. GLP and its principles.

TOTAL: 45 PERIODS

OUTCOME
At the end of the course the students will be able to,
CO1 Illustrate and recognize the design, materials for constructions

CO2 Calculate the cost and capital investment required for the natural and recombinant products development.
CO3 Classify water grade and explain water distribution system
CO4 Explain about validation systems
CO5 Understand the importance of GMP and GLP guidelines.

REFERENCES:

1. G. Vidya Sagar, Text book "Pharmaceutical Industrial Management" 2nd Edition, 2023.
2. Peter, Max S. and Timmerhaus, Klaus D. Plant Design and Economics for Chemical Engineers, 4th ed., McGraw Hill, 1991.
3. A compendium of Good Practices in Biotechnology, BIOTOL Series, Butterworth-Heiemann, 1993
4. Seiler, Jiing P. Good Laboratory Practice: The why and how? Springer, 2001
5. Lydersen, B.K. et al., Bioprocess Engineering: Systems, equipment and facilities, John-Wiley, 1994

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	**2**	**3**	**4**	**5**	**6**
CO1	3	3	2	1	2	3
CO2	-	-	2	1	3	3
CO3	2	3	3	-	2	3
CO4	1	2	3	-	-	2
CO5	3	3	3	2	2	1
Avg	2.25	2.75	2.6	1.33	2.25	2.4

BT3059 HUMAN HEREDITY AND GENETICS L T P C
3 0 0 3

OBJECTIVE
This course aims to provide knowledge on fundamental aspects of human heredity.

UNIT I BACKGROUND, HISTORY AND HEREDITY 9
Introduction to Genetics, Mendelian Genetics. Definitions- Alleles, Phenotypes, Genotypes, Dominance, Incomplete Dominance, co-dominance, Recessiveness, Homozygous, Heterozygous, Hemizygous, Penetrance and Expressivity. Multiple Alleles, ABO blood groups, Bombay phenotype, Epistasis, Pleiotropy. Mendelian inheritance in Humans – Segregation and Independent. Assortment – Marfan Syndrome, Porphyria variegate. Prader – Willi Syndrome and Angelman Syndrome. Types of inheritance, Autosomal Recessive, Autosomal Dominant, Sex-linked Dominant and Sex-linked Recessive. Pedigree Analysis of the different types of inheritance.

UNIT II CYTOGENETICS 9
Human chromosome set. Analyzing chromosomes and Karyotype. Making a karyotype and obtaining cells. Aminocentesis, chorionic villi Sampling-Variation in chromosome number of sets. Polyploidy, Aneuploidy, Autosomal Monosomy, Autosomal trisomy. Risks for autosomal trisomy. Aneuploidy of the sex chromosomes. Turner syndrome, Kleinfelter Syndrome, XYY. Structural Alterations –Deletions and translocations, Fragility and Uniparental Disomy.

UNIT III DEVELOPMENT AND SEX DETERMINATION 9
Sex determination in humans. Human development: Fertilization to Birth. Trimester of Birth. Teratogens, Radiation, Infections agents and Chemicals. Fatal Alcohol Syndrome.

Controlling Reproduction, Contraception and Assisted Reproductive Technologies. Role of environment and chromosomes. Role of Hormones, Androgen insensitivity, Sex testing in sports, Sex phenotype changing and Sex phenotype at puberty. Mutations. Equalizing chromosomes in males and females. Mosaicism, X-inactivation, Expression genes on the X-chromosome. Sex influenced and Sex-limited traits in humans. Mitochondrial inheritance.

UNIT IV POLYGENES AND MULTIFACTORIAL INHERITANCE 9

Polygenes and Variations in phenotype. Additive model. Averaging out the phenotype for polygenic inheritance. Multifactorial inheritance and traits. Effect of the environment. Threshold effect and the expression of multifactorial traits. Interaction between genotype and the environment. Fingerprints to estimate heritability, Twins, homo zygotic and Dizygotic. Skin color, Cardiovascular Diseases-Genetics and Environment. Intelligence and IQ. Searching for genes for intelligence. IQ and Race.

UNIT V GENE MAPPING, TESTING AND BIOETHICS 9

Gene mapping, Testing, Physical mapping, Heteromorphisms, Deletions, Translocation, Dosage mapping. In-situ Hybridization, Somatic Cell hybridization, and positional cloning. Genetic testing and Gene therapy. Clinical Genetics and Genetic counselling. Eugenics and Bioethics.

TOTAL:45 PERIODS

OUTCOME

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

CO1 Understand the fundamental aspects of human heredity
CO2 Explain structural alterations and analyse chromosomes
CO3 Elaborate on Assisted Reproductive technologies
CO4 Describe the interaction between genotype and the environment
CO5 Summarize In situ hybridisation techniques

REFERENCES

1. Tamarin, R.H., “Principles of Genetics”, Tata McGraw Hill, New Delhi, 2002
2. De Robertis, E. D. P. and De Robertis, E. M. F., “Cell and Molecular Biology”, 8th Edition, Lippincott Williams & Wilkins, New York, USA, 2001.
3. Gardner, E.J, Simmons, M.J, and Snustad, D.P., “Principles of Genetics”,8th Edition, John Wiley & Sons, Singapore, 2003.
4. Strickberger, M.W., “Genetics”, 3rd Edition, Prentice Hall of India, New Delhi, 2008.
5. Klug, W.S. and Cummings, M.R., “Concepts of Genetics”, Pearson Education, New Delhi, 2003.

Course Articulation Matrix

Course	Programme Outcome (PO)					
Outcome	**1**	**2**	**3**	**4**	**5**	**6**
CO1	2	-	3	2	-	-
CO2	3	2	-	3	-	-
CO3	3	-	2	3	-	-
CO4	1	2	-	1	-	-
CO5	3	3	-	2	-	-
Avg	2.4	2.33	2.5	2.2	-	-

BP3052 CLINICAL TRIALS AND BIOETHICS L T P C
3 0 0 3

OBJECTIVE

The course aims to,

● Provide fundamental learning about clinical trial management in drug development and project management in clinical trials.

● provide knowledge on pharmacovigilance, quality control and ethical management in clinical research.

UNIT I INTRODUCTION TO CLINICAL TRIALS 9

Fundamentals of clinical trials; Basic statistics for clinical trials; Clinical trials in practice; Reporting and reviewing clinical trials; Legislation and good clinical practice - overview of the European directives and legislation governing clinical trials in the 21 st century; International perspectives; Principles of the International Committee on Harmonisation (ICH)-GCP.

UNIT II REGULATIONS OF CLINICAL TRIALS 9

Drug development and trial planning - pre-study requirements for clinical trials; Regulatory Approvals for clinical trials; Consort statement; Trial responsibilities and protocols - roles and responsibilities of investigators, sponsors and others; Requirements of clinical trials protocols; Legislative requirements for investigational medicinal products.

UNIT III MANAGEMENT AND ETHICS OF CLINICAL TRIALS 9

Project management in clinical trials - principles of project management; Application in clinical trial management; Risk assessment; Research ethics and Bioethics - Principles of research ethics; Ethical issues in clinical trials; Use of humans in Scientific Experiments; Ethical committee system including a historical overview; informed consent; Introduction To ethical codes and conduct; 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.

UNIT IV INFORMED CONSENT 9

Consent and data protection- the principles of informed consent; Consent processes; Data Protection; Legislation and its application; Data management – Introduction to trial master files and essential documents; Data management.

UNIT V QUALITY CONTROL AND GUIDELINES 9

Quality assurance and governance - quality control in clinical trials; Monitoring and audit; Inspections; Pharmacovigilance; Research governance; Trial closure and pitfalls-trial closure; Reporting and legal requirements; Common pitfalls in clinical trial management.

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Acquire knowledge about the fundamentals of clinical trials.

CO2 Understand the guidelines and regulation of clinical trials of new drugs.

CO3 Describe project management in clinical trials and about various ethical issues while conducting clinical trials.

CO4 Explain the importance of an informed consent in clinical trials

CO5 I nterpret the data obtained from clinical trials

REFERENCES

1. Lee, Chi-Jen; etal., “Clinical Trials or Drugs and Biopharmaceuticals.” CRC / Taylor & Francis, 2011.
2. Matoren, Gary M. “The Clinical Research Process in the Pharmaceutical Industry.” Marcel Dekker, 1984.

3. Nardini C. “The ethics of clinical trials”. Cancer medical science. 2014.
4. Ashcroft RE, Viens AM. “The Cambridge Textbook of Bioethics.” Cambridge: Cambridge University; 2008.
5. Bernard Lo, “Ethical Issues in Clinical Research: A Practical Guide”, 2010.

Course Articulation Matrix

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	2	3	2	2	1	2
2	2	3	2	2	1	2
3	2	3	2	2	1	2
4	2	3	2	2	1	2
5	2	3	2	2	1	2
Avg.	2	3	2	2	1	2

BP3051 CHEMISTRY OF NATURAL PRODUCTS L T P C
3 0 0 3

OBJECTIVE
The course aims to enhance theoretical knowledge of students on biosynthetic pathways of different phytoconstituents

UNIT I CARBOHYDRATES AND RELATED COMPOUNDS 9
Sugars and sugar – containing drugs polysaccharides and polysaccharide –containing drugs cellulose gums and mucilages, pectin

UNIT II GLYCOSIDES AND TANNINS 9
Biosynthesis of glycosides, Phenol and alcohol glycosides, anthraquinone glycosides,cyanophore glycosides, saponin glycosides, cardiac glycosides, isothiocyanate flavonol lactone glycosides tannins volatile oils, resins and resin combinations.

UNIT III ALKALOIDS AND ALICYCLIC COMPOUNDS 9
Pyridine and piperidine alkaloids, Tropane alkaloids, Quinoline Alkaloids, isoquinoline alkaloids, Indole alkaloids, Imidazole alkaloids, Steroidal alkaloids, Alkaloidal amines purine bases.Terpenes, camphor, menthol, carotenes.

UNIT IV VITAMINS, PURINES, FLAVONOIDS 9
Chemistry, medicinal and pharmaceutical uses of vitamin A, D, E, K, B1, B2, B6, B12 and Folic Acid.Chemistry and structural elucidation of uric acid, interrelation between caffeine, theophylline and theobromine.Classification and application of flavonoids (hespiridine etc).

UNIT V MOLECULES FROM NATURAL SOURCES 9
Classification of Drug molecules of Plant/marine/microbial and animal sources - cytotoxic / antineoplastic agents, cardiovascular drugs - antimicrobial substances – anti-inflammatory and antispasmodic agents.

TOTAL: 45 PERIODS

OUTCOME
At the end of the course the student will be able to
CO1 Carry out phytochemical tests
CO2 Elaborate on synthesis, medicinal uses of glycosides and tannins
CO3 Describe biosynthetic pathways and uses of alkaloids

CO4 Explain the chemistry, pharmaceutical uses of vitamins and phytoconstituents
CO5 Develop knowledge about natural product based drugs and describe the scientific basis for traditional use of medicinal plants

REFERENCES

1. Evans, W.C., 'Trease and Evans Pharmacognosy', 15thEdition, Saunders, 2002.
2. Wallis, T.E. "Textbook of Pharmacognosy", 5 th Edition, CBS Publishers, 2005.
3. Kokate, C.K. "Pharmacognosy", 29th Edition, Nirali Prakashan, 2004.
4. Bhimsen A. Nagasampagi, Meenakshi Sivakumar, and S.V. Bhat. "Chemistry of Natural Products", 2005.
5. Subhash C. Mandal, Vivekananda Mandal, Tetsuya Konishi, "Natural Products and Drug Discovery - An Integrated Approach", 2018

Course Articulation Matrix

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	2	3	1	2	3	-
2	1	3	2	3	2	1
3	3	2	1	-	3	2
4	3	2	2	1	3	2
5	-	2	1	2	2	3
Avg	2.25	2.4	1.4	2	2.6	2

BC3251 STRUCTURAL BIOLOGY L T P C
3 0 0 3

OBJECTIVES

The aim of this course is to provide knowledge on structural aspects of protein and DNA.

UNIT I STRUCTURE OF MACROMOLECULES – PROTEINS 9

Scope of structural biology – implications, Fundamentals of protein structure, Structural Hierarchy, Motifs and domains: domain structures, Study of prototype protein under each category - alpha, beta, alpha-beta structures, lysozyme, immunoglobulins, thioredoxin, transferases, membrane proteins, structure of viruses

UNIT II STRUCTURE OF MACROMOLECULES – DNA 9

Principles of nucleic acid structure - Watson and Crick's base-pairings and their implications. Non Watson and Crick pairing schemes - base stacking interactions - DNA polymorphism - structure of A-DNA, B-DNA and Z-DNA. Unusual DNA structures - hairpins, bulges, cruciform, triplexes, tetraplexes

UNIT III STRUCTURAL BIOINFORMATICS 9

Methods to secondary structural elements and prediction, Prediction of protein tertiary Structure, Threading, ab initio and Homology Modeling methods, Molecular Docking principles and applications, Protein-protein and Protein-DNA Interactions, Structural genomics

UNIT IV X-RAY CRYSTALLOGRAPHY 9

Elementary crystallography, symmetry in crystals, lattices and unit cells, crystal systems, Bravais lattices, classes of symmetry operations, point groups and space groups, X-ray diffraction - Bragg's law - reciprocal lattice, X-ray scattering: Concept of resolution, Atomic

scattering factor - structure factor equation - electron density and Fourier Transform, solving phases, model building and refinement

UNIT V NMR AND CRYO-ELECTRON MICROSCOPY 9

NMR and its application in Structural Biology, Introduction to the principles of cryo-electron microscopy, – Image formation, aberrations, and beam-induced motion, – Classification, refinement, and reconstruction of 3D models, Sample preparation and practical considerations in cryo-EM, Applications of Cryo-EM in biology

TOTAL: 45 PERIODS

OUTCOMES

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

CO1 Understand structural aspects of DNA
CO2 Classify proteins and explain its design
CO3 Elaborate structural analysis by crystallography
CO4 Analyse X-ray diffraction data
CO5 Understand the principles of NMR and cryo electron microscopy

REFERENCES

1. K.P.Murphy. Protein structure, stability and folding (2001) Humana press. ISBN 0-89603682-0
2. Arthur M.Lesk Introduction to protein architecture (2010) Oxford University Press. ISBN 0198504748
3. A.McPherson, Introduction to Macromolecular Crystallography. 2nd edition (2016)., John Wiley Co.
4. Carl Branden and John Tooze and Carl Brandon Introduction to Protein Structure, (1999) John Garland, Publication Inc. ISBN 0815323050
5. George H. Stout, Lyle H. Jensen, X-Ray Structure Determination: A Practical Guide, 2nd Edition.ISBN 0471607118. 2007
6. Ed Donald J Abraham Wiley-Interscience. Burger's Medicinal Chemistry and Drug discovery. Volume 2, Drug Discovery and development.6th Edition (2003). ISBN 0471370282
7. Crystallography Made Crystal Clear: A Guide for Users of Macromolecular Models, 2006 by Gale Rhodes, Academic Press; 3 edition, ISBN-10: 0125870736, ISBN-13: 978-0125870733
8. The Nuclear Overhauser Effect in Structural and Conformational Analysis, by David Neuhaus Wiley-VCH; 2 edition, 2000, ISBN-10: 0471246751, ISBN-13: 978-0471246756
9. Single-particle Cryo-electron Microscopy: The Path Toward Atomic Resolution/ Selected Papers Of Joachim Frank With Commentaries, World Scientific Publishing Co Pte Ltd, 2018

Course Articulation Matrix:

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	3	2	3	2	3	2
2	3	2	3	2	3	2
3	3	2	3	2	3	2
4	3	2	3	2	3	2
5	3	2	3	2	3	2
Avg.	3	2	3	2	3	2

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

BT3253TECHNIQUES IN MOLECULAR BIOLOGY AND GENETIC ENGINEERING **L T P C**
3 0 0 3

OBJECTIVE

The course aims to provide knowledge on the latest techniques in current biological research as well as in biotechnology industries.

UNIT I VECTOR SYSTEMS 9

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, shuttle vectors.

UNIT II ASSAY TECHNIQUES IN MOLECULAR BIOLOGY 9

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 – siRNA and Morpholino.

UNIT III HIGH-THROUGHPUT DNA SEQUENCING 9

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 9

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 9

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

TOTAL : 45 PERIODS

OUTCOME

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

CO1 Explain about protein purification and artificial chromosomes
CO2 Elaborate the various steps involved in DNA/RNA sequencing methods
CO3 Describe the various steps involved in NGS platforms
CO4 Understand hybridization methods and high throughput analysis
CO5 Develop gene delivery systems

REFERENCES

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

press 2018.
3. Raghavachari Nalini, Garcia-Reyero Natàlia. “Gene expression analysis: Methods and protocols” 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, CSHL press, 2012.

Course Articulation Matrix
MAPPING OF COs WITH POs
Every course outcome must be mapped with 1,2,3 scale against POs

CO-PO MAPPING

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	1	1	1	1	1	1
2	2	1	1	2	1	2
3	3	2	1	2	1	3
4	1	2	1	2	1	3
5	2	2	1	2	1	3
Avg.	1.8	1.6	1	1.8	1	2.4

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO
* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

BT3060 BIOSENSORS AND DIAGNOSTIC APPLICATIONS L T P C
3 0 0 3

OBJECTIVE
The course aims to provide knowledge on emerging trends in medical devices

UNIT I SENSORS AND TRANSDUCERS 9
Rationale of electronic biosensors; Essence of three types of electronic biosensors (i.e., potentiometric, amperometric, and cantilever-based sensors); Three essential metrics that define modern electronic sensors; detection time, sensitivity, and selectivity; Physics of detection time that allows one to organize every available sensor in a systematic way; Fundamental limits of detection of various classes of sensors; Opportunities and challenges of integrating sensors in a system platform. Principles and applications of Calorimetric, Piezoelectric, semiconductor, impedimetric, based transducers; Biochemical Transducers: Electrode theory: electrode-tissue interface, metal- electrolyte interface, electrode-skin interface, electrode impedance, electrical conductivity of electrode jellies and creams.

UNIT II OPTICAL SENSORS AND BIO RECOGNITION SYSTEMS 9
Photo detectors, optical fiber sensors, indicator mediated transducers; General principles of optical sensing, optical fiber temperature sensors; Pulse sensor: photoelectric pulse transducer, strain gauge pulse transducer Enzymes; Oligonucleotides Nucleic Acids; Lipids (Langmuir-Blodgett bilayers, Phospholipids, Liposomes); Membrane receptors and transporters; Immunoreceptors; Chemoreceptors.

UNIT III ELECTRODES AND IMMOBILIZATION 9
Microelectrodes, body surface electrodes, needle electrodes, pH electrode, specific ion electrodes/ Ion exchange membrane electrodes, enzyme electrodes; Reference electrodes: hydrogen electrodes, silver-silver chloride electrodes, Calomel electrodes; Enzyme immobilization; Peptide immobilization; Antibody immobilization; Oligonucleotides and

Nucleic Acid immobilization; Cell immobilization; Mono-enzyme electrodes; Bi-enzyme electrodes: enzyme sequence electrodes and enzyme competition electrodes.

UNIT IV FUNDAMENTALS AND APPLICATIONS OF MICROFLUIDICS 9

Capillary flow and electro kinetics; Micro pump, Micro mixers, Micro reactors, Micro droplets, Micro particle separators; Micro fabrication techniques (different types of lithography methods); Application of micro-fluidics (e.g. Lab- in –Chip).

UNIT V CASE STUDY ON VARIOUS DIAGNOSTIC APPLICATIONS 9

Biomarkers: Disease and pathogen specific information, availability by sample type Applications(blood, serum, urine, sputum, saliva, stool, mucus); Specificity, sensitivity, shelf life, portability; Clinical chemistry; Test-strips for glucose monitoring; Urea determination; Implantable Sensors for long-term monitoring; Drug development and detection; Environmental monitoring; Examples of various diseases (Cancer, HIV/AIDS, Tuberculosis, Malaria, Lymphatic Filariasis, Schistosomiasis, Dengue, Chikungunya).

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Classify and construct biosensors

CO2 Understand the basic configuration of optical sensors and bio-recognition systems

CO3 Summarize the concepts of electrode selection, bio-immobilization and microfluidics

CO4 Elaborate on microfabrication techniques

CO5 Demonstrate diagnostic applications using case studies.

REFERENCES

1. Alice Cunningham, (1998), Introduction to Bio Analytical Sensors, John Wiley & Sons.
2. Jiri Janata, (2009), Principles of Chemical Sensors, 2nd Ed., Plenum Press.
3. F. Schellr, F. Schubert, J. Fedrowitz, (1997), Frontiers in Biosensors, Birkhauser.
4. F. Ligler, C. Rowe Taitt, (2002), Optical Biosensors. Present & Future. Elsevier.
6. Brian Eggins, (2002), Chemical Sensors and Biosensors, John Willey & Sons.
7. Graham Ramsay, (1998), Commercial Biosensors, John Wiley& Sons.
8. Ursula Spichiger-Keller, (1998), Chemical Sensors and Biosensors for Medical and Biological Applications, Wiley-VCH.
9. Berthier Jean, and Silberzan Pascal, (2010), Microfluidics for Biotechnology, 2nd Ed. Artech House.
10. Frank A Gomez, (2008), Biological Applications of Microfluidics, Wiley.
11. Gareth Jenkins, Colin D. Mansfield, (2013), Microfluidic Diagnostics: Methods and Protocols, Springer. 11. J G. Webster, (1998), Encyclopedia of Medical Devices and Instrumentation. Vol I, II, III, IV, Wiley-Blackwell

Course Articulation Matrix: MAPPING OF COs WITH POs

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	2	2	3	3	2	2
2	3	2	2	3	2	2
3	2	2	2	2	2	2
4	2	1	2	2	2	2
5	3	3	3	3	3	2
Avg.	2.4	2	2.4	2.6	2.2	2

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

BT3251 ADVANCED BIOSEPARATION TECHNOLOGY L T PC
3 0 0 3

OBJECTIVES

The course aims to provide knowledge on downstream processing of large biomolecules.

UNIT I GENERAL ASPECTS DOWNSTREAM PROCESS DESIGN AND DEVELOPMENT 9

Introduction to Bioproducts and their Characterization – Purification process flow charting – Economics of Bioproduct Purification – Design of bioseparation process – Thermodynamics - Material and Energy balances -General Schema of Purification strategy – Case studies.

UNIT II INTRODUCTION TO ADSORPTIVE BIOSEPARATIONS 9

Introduction, Theory and chemistry of adsorption. Chromatographic Fundamentals: Retention, Band Spreading, Resolution; Dynamics of Chromatography: Basic mass transfer equations, Method of moments, Linear dispersion model, Linear staged models for chromatography; Instrument Requirements for Chromatography: System design, Column packing techniques; Fundamentals of Adsorption: Gibbs adsorption isotherm, Adsorption isotherm models, Local equilibrium theory and solute movement plots; Expanded bed adsorption.

UNIT III MEMBRANE SEPARATION PROCESSES 9

Principles of membrane separation, Membrane Materials, Transport phenomena of species, molecular and ionic, in porous or dense, charged or not, membranes. Membrane separation processes: Reverse Osmosis, Ultrafiltration, Microfiltration, Nanofiltration, Dialysis, Electrodialysis, Gas Permeation, Pervaporation, Liquid membranes, Membrane modules and design, cost estimation.

UNIT IV CHROMATOGRAPHIC SEPARATION PROCESS DESIGN 9

Preparative Chromatography: Preparative elution, Frontal, Gradient, Displacement chromatography, Optimization; Hydrodynamic design of adsorbent: Particle size, pore size, surface area and pore volume etc. Thermodynamic design of adsorbent: Ligand design through Molecular modeling, retention mechanisms. Modes of Chromatography: Reversed phase and hydrophobic interaction, Ion exchange and Ion exclusion, Size-exclusion, Group specific and biospecific affinity, IMAC, Supercritical fluid chromatography; Isocratic and Gradient Elution preparative chromatography.

UNIT V BIOLOGICAL PRODUCT STABILIZATION AND FORMULATION DEVELOPMENT 9

Factors influencing the peptide and amino acid stability –pre-formulation and development of stability-indicating assays: biophysical characterization techniques- development of a formulation for solid and liquid dosage form - development of a formulation for lyophilized dosage form; Protein Stability During Bioprocessing, Purification, Formulation and Filling; Drying operations - Spray drying - and Freeze drying.

TOTAL: 45 PERIODS

OUTCOMES

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

CO1 Understand physicochemical properties of biotechnological products

CO2 Choose equipment and design mechanical separation process for recovery of biotechnological products.

CO3 Identify and optimize the suitable bioproduct isolation process at laboratory and pilot scale.

CO4 Explain chromatographic separation processes

CO5 Elaborate on stability of biotechnology products

REFERENCES:

1. Roger Harrison, Paul Todd, Scott Rudge and Dimitri Petrides, “Bioseparations Science andEngineering”, Oxford University Press, 2003.
2. Ghosh, Raja “Principles of Bioseparations Engineering”. World Scientific, 2006.
3. Georgios Carta and AloisJungbauer, “Protein Chromatography: Process Development and Scale-up”, Wiley-VCH, 2010.
4. Belter, P.A., E.L. Cussler and Wei-Houhu “Bioseparations – Downstream Processing forBiotechnology”, John Wiley, 1988.
5. Michael C Flickinger, “Encyclopedia of Downstream Industrial Biotechnology”, John Wiley&Sons, 2010.
6. Michael R. Ladisch, Bioseparations Engineering, Wiley Interscience, 2001.

Course Articulation Matrix

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	2	1	1	2	3	-
2	1	1	2	-	3	3
3	2	2	2	-	3	3
4	3	2	2	-	3	3
5	2	3	2	-	3	3
Avg.	2	1.8	1.8	2	3	3

BT3054 GMP AND VALIDATION IN BIOPROCESS INDUSTRIES L T P C
3 0 0 3

OBJECTIVE

The course aims to provide knowledge on current validation practices across the bioprocess industries

UNIT I TRENDS FOR VALIDATING BIOLOGICAL PROCESSES 9

Importance of process validation for manufacturing drugs and medical devices, Definitions, Process validation, Prospective Validation, Concurrent Validation, Retrospective Validation, Critical Process Parameters, Critical Quality Attributes, Scaled-down model, Worst-case, FDA Guidelines

UNIT II PROCESS VALIDATION: GENERAL PRINCIPLES AND PRACTICES 9

General Considerations for Process Validation, Concept of Bioprocess in Bulk Drug Manufacturing, Concept of Biotechniques in industrial validation, Integration of various biotechniques to maintain quality in downstream processing, CGMP regulations for validating biopharmaceutical (drug) manufacturing.

UNIT III GOOD MANUFACTURING PRACTICE FOR BIOPROCESS ENGINEERING 9

Statutory and regulatory requirements for process validation, Production Methods and Considerations, Automation and control issues, System functionality, Principles for Layout of Bulk Production Facilities, Green Field Development, Brown Field Development, cross-contamination from other sources and linked systems, Clean In Place techniques, interactions with shared systems

UNIT IV APPROACH TO PROCESS VALIDATION 9

Process Design, Process Qualification, Continued Process Verification, attributes relating to identity, strength, quality, purity, and potency; Information and data organization from laboratory-, pilot-, and/or commercial-scale studies, validation of computerized systems.

UNIT V CASE STUDIES IN PROCESS VALIDATION 9

Process validation for recombinant therapeutic proteins like erythropoetin, insulin, GMCSF, viral, bacterial vaccines

TOTAL: 45 PERIODS

OUTCOME

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

- understand the implications of validation for process development
- Describe the general principles and practices of process validation of biopharmaceutical manufacturing processes.
- explain regulatory requirements for process validation
- design, verify and validate process using case studies
- analyse the case studies and draw results to the problems

REFERENCES

1. Process Validation in Manufacturing of Biopharmaceuticals, Third Edition, Anurag S. Rathore, Gail Sofer, CRC Press, 2012
2. Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology Phamaceutical Process Validation, Nash, R.A., 2003.
3. Handbook of pharmaceutical analysis. CRC Press, Ohannesian, L. and Streeter, A. eds., 2001
4. Pharmaceutical equipment validation: The ultimate qualification guidebook,Cloud, P., 1998, CRC Press

Course Articulation Matrix: MAPPING OF COs WITH POs

Every course outcome must be mapped with 1,2,3 scale against POs

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	-	3	2	2	1	1
2	-	3	2	2	1	1
3	-	3	2	2	1	1
4	-	3	2	1	1	1
5	-	3	2	1	1	1
Avg.	-	3	2	1.6	1	1

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

BP3055 MOLECULAR MEDICINE AND MECHANISM LT P C

3 0 0 3

OBJECTIVE

The aim of this course is to provide knowledge on the molecular mechanism of the disease

UNIT I INTRODUCTION TO MOLECULAR MEDICINE 9

Organization of the Human Genome, Chromosomes and Genes – Recombinant DNA and Genetic Techniques – Transcriptional Control of Gene Expression – transmission of Human Genetic Disease –Human Genome Project – Cell Cycle Oncogenes and Tumor suppressor

Genes – Molecular Diagnostic Testing – Genetic Counseling – Transgenic Mice as Models of Disease, Introduction to gene therapy

UNIT II CARDIOLOGY 9

Molecular Cardiology Congenital Heart Disease–Inherited Cardiomyopathies–Coronary Atherosclerosis – Endothelium – Derived Nitric Oxide and Control of Vascular Tone – Hypertension – Cardiac Arrhythmias – Cardiovascular Gene Therapy.

UNIT III PULMONOLOGY 9

Asthma – Cystic Fibrosis – Pulmonary Emphysema – Surfactant Deficiency – Lung Cancer: The Role of Tumor Suppressor Genes – Strategies for controlling the diseases.

UNIT IV ENDOCRINOLOGY 9

Mechanisms of Hormone Action – Diabetes Mellitus – Pituitary Function and Neoplasia Hormone Deficiency- Disorders –Thyroid Disorders – Disorders of the parathyroid Gland – Congenital Adrenal Hyperplasia– Adrenal Disease – Multiple Endocrine Neoplasia Type, Mechanisms of Hypoglycemia Associated with increased Insulin Production

UNIT V NEPHROLOGY 9

Renal Development – Mechanisms of Leukocyte Extravasation – Ischemic Acute Renal Failure – Potassium Secretory Channels in the Kidney – Alport Syndrome – Nephrogenic Diabetes Insipidus – Polycystic Kidney Disease – Renal Neoplasms: Wilms' Tumor and Renal-Cell Carcinoma

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Elaborate on human genome and gene therapy.
CO2 Describe cardiovascular diseases and its treatment
CO3 Explain the various strategies to control pulmonary disorders
CO4 Understand the hormone deficiency disorders.
CO5 Summarise renal disorders

REFERENCES

1. Jameson, J. L., Francis, S.C., "Principles of Molecular Medicine", Human Press, 1998.
2. Ross, D.W. "Introduction to Molecular Medicine", 3rdEdition, Springer, 2002.
3. Ross, D.W. "Introduction to Oncogenes and Molecular Medicine", Springer, 1998.
4. Pasternak, J.J. "An Introduction to Human Molecular Genetics", 2nd Edition,Wiley Liss, 2005.
5. Strachan, Tom and Andrew P. Read. "Human Molecular Genetics, Bios, 1996

Course Articulation Matrix

MAPPING OF COs WITH POs

Every course outcome must be mapped with 1,2,3 scale against POs

CO-PO MAPPING

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	2	2	1	2	1	2
2	2	2	1	2	1	2
3	2	2	1	1	1	2
4	2	2	1	2	1	2
5	2	2	1	1	1	2
Avg.	2	2	1	1.6	1	2

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

BC3051 SYNTHETIC BIOLOGY L T P C
3 0 0 3

OBJECTIVES
The course aims to provide knowledge on modern DNA assembly techniques to build biological circuits

UNIT – 1: SYNTHETIC BIOLOGY – BIOLOGICAL COMPONENTS/CIRCUITS 10
Definition and scope, applications of Synthetic biology and milestones in development, principles of artificial gene synthesis, promoters, ribosomal binding sites (RBS), coding sequences and terminators, Logical operators – Repressilator, Toggle-switch, Mammalian tunable synthetic oscillator, Coupled bacterial oscillator , Bacterial tunable synthetic oscillator, Globally coupled bacterial oscillator

UNIT – II:NUMERICAL METHODS FOR SYSTEMS ANALYSIS AND DESIGN 8
Fundamental on the theoretical and computational modelling of replicating systems, Bioinformatic analysis and characterisation of genes and biomolecules, Mathematical model of processes for metabolic pathways and genetic regulatory circuits, Parameter estimation in biochemical pathways, optimal experimental design, dynamic optimization of biosystems.

UNIT – III: METABOLISM OF NUCLEIC ACIDS AND LIPIDS 9
Biosynthesis of nucleotides, *de novo* and salvage pathways for purines and pyrimidines, regulatory mechanisms: Degradation of nucleic acid by exo and endo nucleases. Triacylglycerol and phospholipid biosynthesis and degradation; Cholesterol biosynthesis and regulation and targets and action of cholesterol lowering drugs, statins.

UNIT – IV: FABRICATION OF GENETIC SYSTEMS 9
Introduction to BioBricks and standardization, assembly methods, induction and addition of measurable element, (Eg.GFP) to an existing natural biological circuit, overview and scope of GenoCAD, Clotho framework.

UNIT – V: CASE STUDIES IN ENGINEERED SYSTEMS 9
RNA-based regulatory system for independent control of transcription activities of multiple targets, Applications of Engineered Synthetic Ecosystems, pT181 antisense-RNA-mediated transcription attenuation mechanism and applications, Ethics and patentability,.

TOTAL: 45 PERIODS

OUTCOMES:
At the end of the course the students will be able to
CO1 Understand the principles of artificial gene synthesis
CO2 Optimize experimental design
CO3 Elaborate the numerical methods for system analysis and design.
CO4 Understand fabrication of genetic systems
CO5 Analyse the results and generate testable hypotheses for synthetic biology experiments.

REFERENCES:

1. Synthetic Biology: Tools and Applications by Huimin Zhao, Academic Press; 1 edition (2013), ISBN-10: 0123944309, ISBN-13: 978-0123944306
2. Bioengineering: A Conceptual Approach by MirjanaPavlovic, Springer; 2015 edition, ISBN-10: 3319107976, ISBN-13: 978-3319107974

3. Biological Modeling and Simulation: A Survey of Practical Models, Algorithms, and Numerical Methods (Computational Molecular Biology) by Russell Schwartz, The MIT Press; 1 edition (2008).

Course Articulation matrix

MAPPING OF COs WITH POs

Every course outcome must be mapped with 1,2,3 scale against POs

CO-PO MAPPING

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	3	3	3	2	2	2
2	2	2	2	3	1	2
3	2	2	2	1	1	1
4	3	2	2	3	1	2
5	3	3	3	2	2	2
Avg.	2.6	2.4	2.4	2.2	1.4	1.8

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

BP3001 BIOCONJUGATE TECHNOLOGY AND APPLICATIONS L T P C
3 0 0 3

OBJECTIVE

The course aims to provide knowledge on the importance of Bioconjugate technologies in Biopharmaceuticals

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 ACTIVE GROUPS 9

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

UNIT III BIOCONJUGATE REAGENTS 9

Zero length cross linkers – Homo bifunctional crosslinkers – Hetero bifunctional 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 toDNA – Fluorescent of DNA.

UNIT V BIOCONJUGATE APPLICATIONS 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

OUTCOME

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

CO1 Describe and demonstrate functional target modification
CO2 Predict the chemical reactions based on functional groups
CO3 Understand the importance of cross linkers
CO4 Explain about chemical modification of nucleic acids
CO5 Elaborate on antibody modification

REFERENCES

- Hermanson, G.T. “Bioconjugate Techniques”. Academic Press 3rd edition, 2013
- Bio-synthetic Polymer Conjugates (Advances in Polymer Science by Helmut Schlaad
- Functionalized Redox Systems: Synthetic Reactions and Design of π- and Bio-Conjugates" by Toshikazu Hirao

Course Articulation Matrix:

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	2	2	1	2	1	1
2	2	1	1	1	1	1
3	2	2	2	1	1	1
4	2	3	2	3	1	3
5	2	3	3	3	1	3
Avg.	2	2.2	1.8	2	1	1.8

BT3051 APPLIED GENOMICS AND PROTEOMICS L T P C
3 0 0 3

OBJECTIVES

The course aims to provide theoretical knowledge on the organization and function of genomes

UNIT I ARCHITECTURE OF GENES AND GENOMES 9

Genomic architecture of eukaryotes and prokaryotes. Genomes of organelles (chloroplast, mitochondrion); Characterization of genomes through genetic and physical mapping methods; Fluorescence In-Situ Hybridization (FISH); Comparative Genomic Hybridization (CGH); Whole genome shot-gun sequencing and its applications.

UNIT II LARGE SCALE GENOMICS AND FUNCTIONAL GENOMICS ANALYSES 9

Single nucleotide polymorphism (SNPs) and Genome-wide association (GWA) analysis; Gene expression analysis by cDNA and oligonucleotide arrays; Micro array experimental analysis and data analysis. Methylome analysis using microarray; ChIP-on-Chip analysis. Next Generation Sequencing (NGS) based sequencing of DNA and RNA.

UNIT III ISOLATION AND SEPARATION OF PROTEOME SAMPLES 9

Over-view of strategies used for the identification and analysis of proteins; Protein extraction from biological samples (Mammalian Cells and Tissues, Yeast, Bacteria, and Plant specimen); Two-dimensional Gel-electrophoresis of proteins (2DE) and Difference Gel Electrophoresis (DIGE); Liquid chromatography separations in proteomics (Affinity, Ion Exchange, Reversed-phase, and size exclusion).

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UNIT IV MASS SPECTROMETRY IN PROTEOMICS 9

Introduction to Mass spectrometry; Common ionization methods used for proteomics; Enzymatic cleavage of proteins. Structure and function of MALDI-TOF mass-spectrometry, LC-MS analysis of proteome samples. Protein identification using peptide mass-finger printing and MS/MS strategies.

UNIT V PROTEOMICS THROUGH LARGE-SCALE PROFILING 9

In-vitro and In-vivo labeling of proteins (ICAT and SILAC) followed be mass-spectrometry profiling. Analysis of posttranslational modification (PTM) of proteins; Characterization of protein-protein interactions using yeast two-hybrid system, Protein microarrays and its applications; Proteomics informatics and analysis of protein functions.

TOTAL: 45 PERIODS

OUTCOMES:

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

CO1 Elaborate on the organization and function ofgenomes

CO2 Describe functional genomics analyses

CO3 Decide appropriate methods for isolation and separation of proteomes

CO4 Explain the structure and function of mass-spectrometers

CO5 Summarize different proteomics approaches involving large-scale protein profiling

REFERENCES:

1. S.P. Hunt and F. J. Livesey, (2000) Functional Genomics, OxfordUniversity press
2. N. K. Spur, B. D. Young, and S. P. Bryant (1998) ICRF Handbook of Genome Analysis Volume 1 & 2, Black well publishers
3. G. Gibson and S. V. Muse, 3rd ed., (2009) A primer of Genome Science, Sinauer Associates, Inc. Publishers
4. R. J. Reece (2004) Analysis of Genes and Genomes, John Wiley & SonsLtd
5. Rinaldis E. D. and Lahm A (2007) DNA Microarrays. Horizon bioscience.
6. Simpson R. J."Proteins and Proteomics - A Laboratory Manual".Cold Spring Harbour Laboratory Press, 2002.
7. Twyman R. M. "Principles of Proteomics". Taylor & Francis. 2004
8. O'Connor C. D. and Hames B. D. "Proteomics". Scion, 2008.
9. Schena M. "Protein Microarrays". Jones and Bartlett, 2005.
10. Smejkal G. B. and Lazarev A. V. "Separation methods in Proteomics". CRC Press,2006.

Course Articulation Matrix

Course Outcome	Programme Outcome (PO)					
	1	2	3	4	5	6
CO1	-	3	1	2	3	-
CO2	3	3	2	1	3	2
CO3	3	2	1	3	2	2
CO4	2	2	1	2	3	3
CO5	2	2	1	2	2	3
Overall CO	2	2	1	2	3	3

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

BT3055 METABOLIC ENGINEERING L T P C

3 0 0 3

OBJECTIVE

The course aims to familiarize the student with quantitative approaches for analyzing cellular metabolism and make the students aware of the structure and regulation of metabolic networks.

UNIT I METABOLIC FLUX ANALYSIS 9

Introduction to metabolic engineering, comprehensive models of cellular reactions with stoichiometry and reaction rates; metabolic flux analysis of exactly determined systems for lactic acid ,citric acid and systems, Shadow price, sensitivity analysis

UNIT II TOOLS FOR EXPERIMENTALLY DETERMINING FLUX THROUGH PATHWAYS 9

Monitoring and measuring the metabolome, Methods for the experimental determination of metabolic fluxes by isotope labelling of linear, branched and cyclic pathways using NMR, metabolic fluxes using various separation-analytical techniques. GC-MS for metabolic flux analysis, genome wide technologies: DNA /phenotypic microarrays and proteomics.

UNIT III CONSTRAINT BASED GENOMIC SCALE METABOLIC MODEL 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 IV METABOLIC CONTROL ANALYSIS AND KINETIC MODELING 9

Metabolic Control Analysis, control coefficients and the summation theorems, Determination of flux control coefficients. Multi-substrate enzyme kinetics, engineering multifunctional enzyme systems for optimal conversion, and a multi scale approach for the predictive modeling of metabolic regulation.

UNIT V CASE STUDIES IN METABOLIC ENGINEERING 9

Metabolic engineering examples for bio-fuel, bio-plastics and green chemical synthesis. Identification of rational targets by elementary mode analysis and genome scale model in various systems for the production of green chemicals using software tools. Validation of the model with experimental parameters.

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Identify the optimal strategy for introducing genetic changes in the microorganisms with the aim of obtaining better production strains.

CO2 Elaborate on metabolic flux analysis by NMR and GCMS

CO3 Decribe about the databases for genome scale modelling

CO4 Elaborate the predictive modeling of metabolic regulation

CO5 Understand the concept of green chemical synthesis

REFERENCES

1. Stephanopoulos, G.N. “Metabolic Engineering: Principles and Methodologies”. Academic Press / Elsevier, 1998.
2. Lee, S.Y. and Papoutsakis, E.T. “Metabolic Engineering”. Marcel Dekker, 1998.
3. Nielsen, J. and Villadsen, J. “Bioreaction Engineering Principles”. Springer, 2007.
4. Smolke, Christiana D., “The Metabolic Pathway Engineering Handbook Fundamentals”, CRC Press Taylor & Francis, 1st edition 2010.
5. Voit, E.O. “Computational Analysis of Biochemical Systems : A Practical Guide for Biochemists and Molecular Biologists”. Cambridge University Press, 1st edition 2000.

Course Articulation Matrix

MAPPING OF COs WITH POs

Every course outcome must be mapped with 1,2,3 scale against POs

CO-PO MAPPING

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	2	2	2	2	1	1
2	2	2	2	2	1	2
3	2	2	2	1	1	3
4	2	1	2	1	1	2
5	2	2	2	2	1	3
Avg.	2	1.8	2	1.6	1	2.2

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

BP3002 ADVANCES IN PHARMACOGENOMICS L T P C
3 0 0 3

OBJECTIVE
The course aims to provide knowledge on the role of Pharmacogenomics in drug design and development.

UNIT I INTRODUCTION TO PHARMACOGENOMICS 9
Pharmacogenetics-The roots of pharmacogenomics, Genetic drug response profiles, the effect of drugs on Gene expression, pharmacogenomics in drug discovery and drug development.

UNIT II THE HUMAN GENOME 9
Expressed sequence Tags (EST) and computational biology, Microbial genomics, computational analysis of whole genomes, computational genome analysis, Genomic Differences that affect the outcome of host pathogen interactions: A template for the future of whole genome-based pharmacological science.

UNIT III ASSOCIATION STUDIES IN PHARMACOGENOMICS 9
Viability and ADR in drug response: contribution of genetic factor, Multiple inherited genetic factors influence the outcome of drug treatments, Plasma binding proteins, Drug targets.

UNIT IV GENOMICS APPLICATIONS FOR DRUG ACTION AND TOXICITY 9
Genomics, Proteomics, Bioinformatics, The pharmaceutical process, applications-pharmaceutical industry, Understanding biology and diseases, Target identification and validation, Drug candidate identification and optimization.

UNIT V PHARMACOGENOMICS AND DRUG DESIGN 9
The need of protein structure information, protein structure and variation in drug targets-the scale of problem, Mutation of drug targets leading to change in the ligand binding pocket.

TOTAL: 45 PERIODS

OUTCOME
At the end of the course the student will be able to,
CO1 Learn about the human genome, gene expression and their effect on drug therapy
CO2 Understand the genomic differences that affect the host pathogen interactions
CO3 Elaborate on genetic factors influencing drug response
CO4 Elaborate on target identification and validation.
CO5 Explain the importance of pharmacogenomics in drug design

REFERENCES

1. Licinio, Julio and Ma-Li Wong, “Pharmacogenomics: The Search for the Individualized Therapies”, Wiley-VCH, 2002.
2. Chiranjib Chakraborty and Atana Bhattacharyya, “Pharmacogenomics: An Approachto New Drugs Development”, 2004. 3. Rothstein, Mark, A. “Pharmacogenomics: Social, Ethical and Clinical Dimensions”, Wiley- Liss, 2003.
3. Urs A.Meyer, F.Marcus Rattray, Richard M.Weinshilboum ”Pharmacogenomics: Challenges and Oppurtunities in Therapeutic Implementation”, 1 st edition , 2013
4. Joseph S.Bertino, Wiliiam E.Evans “Pharmcogenomics : An introduction and clinical Perspective”, 2nd edition, 2013
5. Dennis A.Smith, Edward J.Boyer ” Principles of Pharmacogenetics and Pharmacogenomics”, 2nd edition, 2012

Course Articulation Matrix

Every course outcome must be mapped with 1,2,3 scale against POs

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	2	2	1	2	1	1
2	2	1	1	1	1	1
3	2	2	2	1	1	1
4	2	3	2	3	1	3
5	2	3	3	3	1	3
Avg.	2	2.2	1.8	2	1	1.8

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

BP3003 CONVENTIONAL AND RATIONAL DRUG DISCOVERY STRATEGIES L T P C

3 0 0 3

OBJECTIVES

The course aims to expose the students to various principles and methodologies involved in drug discovery.

UNIT I FUNDAMENTALS ON RATIONAL DRUG DESIGN 9

Various approaches in drug discovery process – conventional versus rational, drug targets, lead identification; Principles of ligand chemistry – lead optimization, pharmacophores, bioisosteres, principles of ligand chemistry such as configuration, conformation, chirality, isosteric replacement; Parameters of ligand design such as –Phytochemical, geometric, conformational, topological, partitional, steric, stereochemical and electronic properties of drug molecules; Pharmacokinetic parameters of ligand design such as - lipinski “rule of 5”, partition coefficient, hammet constant, hansch analysis. biological, chemical and physical descriptors used in qsar and qspr. statistical methods used for analysing QSAR/ QSPR data

UNIT II IN-SILICO AND SIMULATION METHODOLOGIES IN DRUG DISCOVERY 9

Introduction to molecular docking (including methods and scoring functions), de novo pharmacophore elucidation/ drug design for structurally well-defined receptor targets from case studies (Eg. HIV protease inhibition, ACE inhibition); Principles of macromolecule-ligand docking, docking algorithms, AUTODOCK; Molecular dynamic simulations, relative energy, energy minimization methods, ligand binding free energy calculations (both simulation and empirical methods), intermolecular interactions, forces related to drug

binding, force-field calculations including solution, role of solubility in drug binding and pKa, Poisson-Boltzmann Surface Area (PBSA), AMBER, GROMOS and GROMACS.

UNIT III COMBINATORIAL AND SYNTHETIC PEPTIDE LIBRARIES 9

Combinatorial Chemistry in drug development, Biopolymers as natural libraries, Selection and evolution of expression genetic libraries, Combinatorial assembly of antibody genes, Molecular solutions to Combinatorial problems, Solid-Phase peptide synthesis, Peptide on pins, Other iterative deconvolution strategies, Examples of Split/Couple/Mix Peptide Libraries, Positional Scanning., Polystyrenes, Grafted supports, Coupling strategies, linkers, Supported Solution and Phase Synthesis, analytical methods for solid-phase

UNIT IV HIGH THROUGHPUT SCREENING IN DRUG DISCOVERY 9

Classification of HTS: Protein based biochemical screens, methods of analytical biochemistry used in HTS (photometry, purification, electrophoresis, kinetic assay, radioisotopes, immunoassay, HTS FACS based assays). Assay design for HTS and statistical treatment of the results for decision. Introduction to state of the art technologies used in HTS (including automated liquid handling machines (robots), Microfluidic Tools for HTS, Miniaturization); preclinical toxicological studies, Correlation between in-vitro and in-vivo screens, case studies on pharmacological screening models for therapeutic areas such as hypertension, Parkinson's disease, Alzheimer's disease, diabetics, parasitic diseases

UNIT V GENETIC BASED TOOLS IN DRUG DISCOVERY PROCESS 9

Basics of gene silencing, transgenic worms in drug screening; designing SiRNAs, Types of RNAi Screens – Loss of Function screens (LOF), Synthetic Lethal screen, Mini-clonogenic RNAi screen; optimizing, and implementing high-throughput siRNA genomic screening for the discovery of survival genes and novel drug targets, siRNA HTS Screening for identification of targeted pathways in biological systems. Microarray technologies – Classification with microarrays and class prediction, Visualization and functional analysis. Bio molecular pathways, gene ontology, genome browsing, Gene expression biology, microarray platforms, design of experiments, file structures and data storage (Eg.Affymetrix); Preprocessing of microarray data for Image analysis, quality control and array normalization.

TOTAL :45 PERIODS

COURSE OUTCOMES:

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

CO1 Describe the various approaches used in drug discovery process and explain pharmacokinetic parameters of ligand based design

CO2 Understand the importance of molecular modeling in drug development

CO3 Analyse and provide solutions to combinatorial problems

CO4 Summarize technologies used in HTS

CO5 Elaborate on microarray technologies

REFERENCES

1. Williams, D.A. and Lemke, T.L., "Foye's Principles for Medicinal Chemistry" 5th Edition, Lippincott, Williams & Wilkins, 2002.
2. Leach, AR, "Molecular Modeling & Drug Design", 2nd Edition, John Willy, 2000.
3. GROMOS and GROMACS Manuals.
4. Murray, K.J. "Principles and Practice of High Throughput Screening". Blackwell Scientific Publishers, 2004.
5. Ye, S., and Day, I.N.M. "Microarrays and Microplates: Applications in Biomedical Sciences". BIOS 2003.
6. "Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry".12th Edition, Lippincott-Raven Publisher, 2010.
7. Fassina, G. "Combinatorial Chemistry and Technologies: Methods and Applications", 2ndEdition, CRC Press, 2005

8. Block J.H. and Beale, J.M., 'Wilson & Gisvolds Textbook of Organic Medicinal and Pharmaceutical Chemistry', 11th Edition, Lippincott Williams & Wilkins, 2004.
9. Janzen W. P. "High Throughput Screening: Methods and protocols". Humana Press. 2002

Course Articulation Matrix

MAPPING OF COs WITH POs

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	3	3	3	2	2	2
2	2	2	2	3	1	2
3	2	2	2	1	1	1
4	3	2	2	3	1	2
5	3	3	3	2	2	2
Avg.	2.6	2.4	2.4	2.2	1.4	1.8

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

BP3053 MOLECULAR DIAGNOSTICS L T P C
3 0 0 3

OBJECTIVES
The course aims to

- sensitize students about recent advances in molecular biology and various facets of molecular medicine.
- Make them utilize the techniques of molecular medicine for pre- or post-natal analysis of genetic diseases and identification of individuals predisposed to disease ranging from common cold to cancer.

UNIT I GENOME BIOLOGY: HEALTH, DISEASE DETECTION AND ANALYSIS 9
DNA, RNA and Protein: An overview; chromosomal structure & mutations; DNA polymorphism: human identity; clinical variability and genetically determined adverse reactions to drugs. PCR: Real-time; ARMS; Multiplex; ISH; FISH; ISA; RFLP; DHPLC; DGGE; CSCE; SSCP; Nucleic acid sequencing: new generations of automated sequencers; Microarray chips; EST; SAGE; microarray data normalization & analysis; molecular markers: 16S rRNA typing; Diagnostic proteomics: SELDI-TOF MS; Bioinformatics data acquisition & analysis.

UNIT II DIAGNOSTIC METABOLOMICS 9
Metabolite profile for biomarker detection in the body fluids/tissues under various metabolic disorders by making use of LCMS & NMR technological platforms

UNIT III DETECTION AND IDENTITY OF MICROBIAL DISEASES 9
Direct detection & identification of pathogenic-organisms that are slow growing or currently lacking a system of in vitro cultivation as well as genotypic markers of microbial resistance to specific antibiotics.

UNIT IV DETECTION OF INHERITED DISEASES 9
Exemplified by two inherited diseases for which molecular diagnosis has provided a dramatic improvement of quality of medical care: - Fragile X Syndrome: Paradigm of the new

mutational mechanism of the unstable triplet repeats, von-Hippel Lindau disease: recent acquisition in the growing number of familial cancer syndromes.

UNIT V MOLECULAR ONCOLOGY AND QUALITY ASSURANCE AND CONTROL9

Detection of recognized genetic aberrations in clinical samples from cancer patients; types of cancer-causing alterations revealed by next-generation sequencing of clinical isolates; predictive biomarkers for personalized onco-therapy of human diseases such as chronic myeloid leukemia, colon, breast, lung cancer and melanoma as well as matching targeted therapies with patients and preventing toxicity of standard systemic therapies. Quality oversight; regulations and approved testing.

TOTAL:45 PERIODS

OUTCOMES:

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

CO1 Understand various facts of molecular procedures and basics of genomics, proteomics and metabolomics that could be employed in early diagnosis and prognosis of human diseases.

CO2 Elaborate on biomarker detection in body fluids

CO3 Identify and detect pathogenic micro-organisms

CO4 Design the biomedical tool for the detection of inherited diseases

CO5 Develop molecular diagnostics tools for the detection of cancer

REFERENCES

1. Campbell, A. M., & Heyer, L. J. (2006). Discovering Genomics, Proteomics, and Bioinformatics. San Francisco: Benjamin Cummings
2. Brooker, R. J. (2009). Genetics: Analysis & Principles. New York, NY: McGraw-Hill.
3. Glick, B. R., Pasternak, J. J., & Patten, C. L. (2010). Molecular Biotechnology: Principles and Applications of Recombinant DNA. Washington, DC: ASM Press.
4. Coleman, W. B., & Tsongalis, G. J. (1997). Molecular Diagnostics: for the Clinical Laboratorian. Totowa, NJ: Humana

Course Articulation Matrix

MAPPING OF COs WITH POs

Every course outcome must be mapped with 1,2,3 scale against POs

CO	PO					
	1	**2**	**3**	**4**	**5**	**6**
1	2	2	3	3	2	2
2	3	2	2	3	2	2
3	2	2	2	2	2	2
4	2	1	2	2	2	2
5	3	3	3	3	3	2
Avg.	2.4	2	2.4	2.6	2.2	2

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.