ANNA UNIVERSITY, CHENNAI

UNIVERSITY DEPARTMENTS

REGULATIONS – 2015

CHOICE BASED CREDIT SYSTEM

M. Tech. BIOPHARMACEUTICAL TECHNOLOGY

PROGRAMME EDUCATIONAL OBJECTIVES (PEOs) :

I. To prepare students to excel in research and to succeed in Biopharmaceutical technology profession through global, rigorous post graduate education.
II. To provide students with a solid foundation in statistical, scientific and engineering fundamentals required to solve biopharmaceutical related problems
III. To train students with good scientific and technical knowledge so as to comprehend, analyze, design, and create novel products and solutions for the health related problems.
IV. To inculcate students in Scientific & professional ethics, scientific communication skills, teamwork skills, multidisciplinary approach, and an ability to address health related problems to broader social context.
V. To provide student with an academic environment aware of excellence, leadership, written ethical codes and guidelines, and the life-long learning needed for a successful Scientific and professional career.

PROGRAMME OUTCOMES (POs):

On successful completion of the programme,

1. Graduates will demonstrate knowledge of statistics, science and technology.
2. Graduates will demonstrate an ability to identify, formulate and solve health related issues.
3. Graduate will demonstrate an ability to design and conduct experiments, analyze and interpret data.
4. Graduates will demonstrate an ability to design an experiment, component or process as per needs and specifications.
5. Graduates will demonstrate an ability to visualize and work on laboratory and multidisciplinary tasks.
6. Graduate will demonstrate skills to employ modern technology, software and equipment to analyze problems.
7. Graduates will demonstrate knowledge of professional and ethical responsibilities.
8. Graduate will be able to exhibit scientific communication effectively in both verbal and written form.
9. Graduate will show the understanding of impact of pharmaceutical technology on the society and also will be aware of contemporary issues.
10. Graduate will develop confidence for self education and ability for life-long learning.

Attested

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Programme Educational Objectives	Programme Outcomes									
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
I	✓	✓		✓						
II					✓	✓	✓			
III				✓	✓	✓	✓			
IV							✓	✓	✓	
V		✓	✓						✓	✓

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			PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
YEAR 1	SEM 1	Applied statistics for Biologists	✓	✓	✓							
		Pharmacokinetics and pharmacodynamics	✓		✓	✓	✓					
		Biogenerics and Biopharmaceuticals	✓	✓	✓	✓	✓					
		Advanced Genetic Engineering	✓		✓	✓	✓	✓				
		Elective – 1										
		Elective – 2										
		Elective – 3										
		Formulation and Analytical Techniques in Biopharmaceutical Technology			✓	✓	✓	✓				
	SEM 2	Drug dosage forms and design		✓	✓	✓	✓					
		Drug Regulatory, Quality and Safety evaluation		✓	✓	✓	✓		✓		✓	
		Immunopharmacology	✓	✓				✓				
		Fermentation technology			✓	✓	✓	✓				
		Elective – 4										
		Elective – 5										
		Elective – 6										
		Immunopharmacology			✓	✓	✓	✓				
YEAR 2	SEM 3	Project work (Phase – I)		✓		✓			✓			✓
		Drug discovery lab				✓		✓	✓	✓	✓	✓
	SEM 4	Project Work (Phase – II)				✓		✓	✓	✓	✓	✓

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I – IV SEMESTER CURRICULUM AND SYLLABUS

M. TECH. BIOPHARMACEUTICAL TECHNOLOGY

Sl.No	Course Code	Course Title	Category	Contact Periods	L	T	P	C
SEMESTER - I								
Theory								
1.	BT7152	Applied statistics for Biologists	FC	4	4	0	0	4
2.	BP7102	Pharmacokinetics and Pharmacodynamics	PC	3	3	0	0	3
3.	BP7101	Biogenerics and Biopharmaceuticals	PC	3	3	0	0	3
4.	BT7151	Advanced Genetic Engineering	PC	3	3	0	0	3
5.		Elective I	PE	3	3	0	0	3
6.		Elective II	PE	3	3	0	0	3
7.		Elective III	PE	3	3	0	0	3
Practicals								
8.	BP7111	Formulation and Analytical Techniques in Biopharmaceutical Technology	Lab	6	0	0	6	3
			TOTAL	**28**	**22**	**0**	**6**	**25**

Sl.No	Course Code	Course Title	Category	Contact Periods	L	T	P	C
SEMESTER – II								
Theory								
1.	BP7201	Drug dosage forms and design	PC	3	3	0	0	3
2.	BP7202	Drug Regulatory, Quality and Safety evaluation	PC	3	3	0	0	3
3.	BP7204	Immunopharmacology	PC	3	3	0	0	3
4.	BP7203	Fermentation technology	PC	3	3	0	0	3
5.		Elective IV	PE	3	3	0	0	3
6.		Elective V	PE	3	3	0	0	3
7.		Elective VI	PE	3	3	0	0	3
Practicals								
8.	BP7211	Immunopharmacology Lab	PC	6	0	0	6	3
			TOTAL	**27**	**21**	**0**	**6**	**24**

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Sl.No	Course Code	Course Title	Category	Contact Periods	L	T	P	C
SEMESTER - III								
1.	BP7311	Drug Discovery lab	Lab	6	0	0	6	3
2.	BP7312	Project Work Phase – I	EEC	12	0	0	12	6
			TOTAL	**18**	**0**	**0**	**18**	**9**

Sl.No	Course Code	Course Title	Category	Contact Periods	L	T	P	C
SEMESTER – IV								
1.	BP7411	Project Work Phase – II	EEC	24	0	0	24	12
			TOTAL	**24**	**0**	**0**	**24**	**12**

TOTAL NO OF CREDITS : 70

Foundation Courses (FC)

S.No	COURSE CODE	COURSE TITLE	CATEGORY	CONTACT PERIODS	L	T	P	C
THEORY								
1.		Applied statistics for Biologists	FC	4	4	0	0	4

Professional Core (PC)

S.No	COURSE CODE	COURSE TITLE	CATEGORY	CONTACT PERIODS	L	T	P	C
THEORY								
1.		Pharmacokinetics and pharmacodynamics	PC	3	3	0	0	3
2.		Biogenerics and Biopharmaceuticals	PC	3	3	0	0	3
3.		Advanced Genetic Engineering	PC	3	3	0	0	3
4.		Drug dosage forms and design	PC	3	3	0	0	3
5.		Drug Regulatory, Quality and Safety evaluation	PC	3	3	0	0	3
6.		Immunopharmacology	PC	3	3	0	0	3
7.		Fermentation technology	PC	3	3	0	0	3

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Professional Electives (PE)

S.No	COURSE CODE	COURSE TITLE	CATEGORY	CONTACT PERIODS	L	T	P	C
THEORY								
1.	BT7071	Advanced Genomics and Proteomics	PE	3	3	0	0	3
2.	BT7072	Advanced Technologies in Omics Sciences	PE	3	3	0	0	3
3.	BT7073	Advances in Molecular Pathogenesis	PE	3	3	0	0	3
4.	BT7074	Biocatalysts and Enzyme Technology	PE	3	3	0	0	3
5.	BP7001	Bioconjugate Technology and Applications	PE	3	3	0	0	3
6.	BP7002	Chemistry of Natural Products	PE	3	3	0	0	3
7.	BP7003	Clinical Trials and Bioethics	PE	3	3	0	0	3
8.	BT7075	Communication Skill development	PE	3	3	0	0	3
9.	BP7004	Conventional and rational Drug Discovery Strategies	PE	3	3	0	0	3
10.	BT7076	Metabolic Process and Engineering	PE	3	3	0	0	3
11.	BP7005	Molecular Medicine and Mechanism	PE	3	3	0	0	3
12.	BT7077	Nanobiotechnology	PE	4	2	0	2	3
13.	BP7071	Pharmacogenomics	PE	3	3	0	0	3
14.	BT7078	Research and Research Methodology in Biotechnology	PE	3	3	0	0	3

Employability Enhancement Courses (EEC)

S.No	COURSE CODE	COURSE TITLE	CATEGORY	CONTACT PERIODS	L	T	P	C
THEORY								
1.		Project Phase - I	EEC	8	0	0	8	6
2.		Project Phase - II	EEC	24	0	0	24	12

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BT7152 APPLIED STATISTICS FOR BIOLOGISTS

L	T	P	C
4	0	0	4

OBJECTIVES

This subject will facilitate the students to understand the fundamentals of statistics for biologists.

OUTCOME

On the completion of the course the students are expected to have learnt, Understanding and applying Statistical methods of analysis for Biological applications.

UNIT I **12**

Random variable-sample spaces-Events-Axiomatic approach to probability-conditional probability-additional theorem, Multiplication theorem -Baye's theorem problems-continuous and discrete random variables, Distribution function-Expectation with properties-Moments, mean, Variance problems-for continuous and discrete distributions.

UNIT II **12**

Bivariate distribution-conditional and marginal distribution-Discrete distribution-Binomial, Poisson, geometric distribution-Continuous distribution, Normal, exponential and negative exponential, gamma distributions-simple problems-properties.

UNIT III **12**

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

UNIT IV **12**

Concept of sampling-Methods of sampling-sampling distributions and Standard Error-Small samples and large samples-Test of hypothesis-Type I, Type II Errors-Critical region-Large sample tests for proportion, mean-Exact test based on normal , t, f and chi-square distribution-problems-Test of goodness of fit.

UNIT V **12**

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

TOTAL : 60 PERIODS

TEXT BOOKS

1. Kapoor, V. C. "Elements of Mathematical statistics".
2. Vittal, P.R. and V.Malini."Statistical and Numerical Methods". Margham Publications.
3. Veerarajan,T. "Probability, Statistics and Random Processes".3rd Edition., Tata McGraw-Hill, 2008.

REFERENCES

1. Johnson, R. A."Miller& Freund's Probability and Statistics for Engineers". 6th ed. PHI, 2003.
2. Arora, P. N. SmeetArora, and Arora, S. "Comprehensive Statistical Methods". S. Chand & Co,
3. Spiegel, Murray R., J.Schiller and R.AluSrinivasan."Schaum's Outlines Probability and Statistics".2nd Edition. Tata McGraw-Hill 2000.
4. Kandasamy, P. K. Thilagavathi& K. Gunavathi."Probability Statistics and Queuing Theory". S. Chand & Co., 2004.

BP7102 PHARMACOKINETICS AND PHARMACODYNAMICS

L	T	P	C
3	0	0	3

OBJECTIVES

This subject will enable the students to understand the essential principles of pharmacokinetics and pharmacodynamics required for the development of therapeutic agents.

OUTCOME

On the completion of the course the students are expected to have understood and learnt the fundamentals drug PK/PD that will enable them for research and application in dosage form development.

UNIT I FUNDAMENTALS ONDRUG ABSORPTION AND DISTRIBUTION 9

Definitions, various routes of administrationwith 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 ONDRUG 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 10

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 APPLICATION OF PD/PK PRINCIPLES IN DOSAGE FORM DEVELOPMENT 8

Regimens for dosage form design, concentration response relationships, individualization therapeutics, classification of controlled release formulations and novel drug delivery (oral, parenteral, trans-dermal, ophthalmic and intrauterine) systems, bioavailability testing of novel release formulations.

TOTAL : 45 PERIODS

TEXT BOOKS

1. Brahmankar, D.M., “Biopharmaceutical and Pharmacokinetics:A Treatise”, VallabhPrakashan, 1995
2. Notari, R.E., “Biopharmaceutics and Clinical Pharmacokinetics: An Introduction”, 4th Edition, MarcellDeckker, 2005

REFERENCES

1. Schoenwald, R.D., “Pharmacokinetics in Drug Discovery and Development”, CRC Press,2002.
2. Oliver Kayser, Rainer H. Müller, “Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications”, Wiley-VCH publications

BP7101	BIOGENERICS AND BIOPHARMACEUTICALS	L	T	P	C
		3	0	0	3

OBJECTIVES

To introduce the students about biogenerics and biosimilars and their characterization usinganalytical methods and presumptions of therapeutic equivalence along with case studies.

OUTCOME

The subject will give exposure of fundamental knowledge in biogenerics, biosimilar andbiopharmaceuticals for students to make their career in pharmaceutical industries.

UNIT I BIOGENERICS INTRODUCTION 9

Definition: Generics and its advantages; Biogenerics and Biosimilars; Why biosimilars arenot (bio) generics; The advent of Biosimilars; The role of patents in the drug industry;Protein-based biopharmaceuticals; Manufacturing processes; Global market; InternationalNon-proprietary Names (INN) nomenclature system biosimilars regulation (EU position, USpathways, Government initiatives)

UNIT II BIOSIMILARS AND ITS SCENARIO 9

Approved follow-on proteins/Biosimilars; Characteristics of highselling peptides andproteins,; Products with expired patents; Challenging originator’s patents; Target productsfor FOB (follow-on biologicals)/Biosimilars development peptides; Recombinantnonglycosylated proteins; Recombinant glycosylated proteins; Industries dealing withbiogenerics 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, Monoclonalantibodies); Equivalence issues; Post-translational modifications; Effect ofmicroheterogeneity; Pharmacokinetics; Pharmacodynamics; and Clinical efficacy; Analyticalmethods for the characterization of biosimilars (Chromatography, Protein sequencing, Massspectrometry, UV absorption, Circular dichroism, X-ray techniques, Nuclear magneticresonance, Electrophoresis, Western blotting, Bioassays, ELISA, Immunoprecipitation andother procedures)

UNIT IV IMMUNOGENECITY OF BIOPHARMACEUTICALS 9

Immunogenicity of biopharmaceuticals: Immunogenicity; Factors contributing toimmunogenicity

(product-related f actors, host- related factors), Consequence ofimmunogenicity 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, Tissueplasminogen activator, Monoclonal antibodies etc.

TOTAL : 45 PERIODS

TEXTS/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".

BT7151 ADVANCED GENETIC ENGINEERING **L T P C**
3 0 0 3

OBJECTIVE

This subject provides conceptual knowledge in the Cloning & Expression of genes;Construction of DNA libraries & Sequencing; PCR & mutagenesis; Gene transfer & Genetherapy to students.

OUTCOME

Students will learn advanced molecular methods to help them design and execute complexmolecular Biology experiments.

UNIT I CLONING AND EXPRESSION OF GENES **10**

Overview of Restriction and Modification system. Cloning vehicles: Plasmids – Host range,Copy number control, Compatibility. λ phage – Insertional and Replacement vectors,*in vitro*packaging. Single strand DNA vector – M13 Phage. Cosmids, Phasmids, PAC, BAC and YAC. Expression vector – Characteristics, RNA probe synthesis, High level expression ofproteins, Protein solubilization, purification and export.

UNIT II CONSTRUCTION OF DNA LIBRARIES **10**

DNA library – Types and importance. cDNA library: Conventional cloning strategies – OligodT priming, self-priming and its limitations. Full length cDNA cloning – Capture method andOligo capping. Strategies for gDNA library construction – Chromosome walking. Differencesbetween gDNA and cDNA library. Screening strategies – Hybridization, PCR,Immunoscreening, South-western and North-Western. Functional cloning – Functionalcomplementation and gain of function. Difference cloning: Differential screening, SubtractedDNA library, differential display by PCR. Overview on microarray and its applications.

UNIT III DNA SEQUENCING **8**

DNA sequencing – Importance, Chemical & Enzymatic methods, Pyrosequencing,Automated sequence, Genome sequencing methods – top down approach, bottom upapproach.

UNIT IV PCR AND MUTAGENESIS **9**

PCR – Principle and applications. Different types of PCR – Hot start PCR, Touchdown PCR,Multiplex PCR, Inverse PCR, Nested PCR, AFLP-PCR, Allele specific PCR, Assembly PCR,Asymmetric PCR, LATE-PCR, Colony PCR,*in situ*PCR, Long P CR. Real-time PCR – SYBRGreen assay, Taqman Probes, Molecular beacons. Mutagenesis and chimeric proteinengineering by PCR, RACE, Kuntels' method of mutagenesis.

UNIT V GENE TRANSFER & GENE THERAPY **8**

Introduction of foreign genes into animal cells – Importance, DNA Microinjection, Retroviralvectors, Trasnsfection of Embryonic stem cells, recombination. Transgenic plants – Importance, Ti Plasmid, Cointegrate and Binary vectors. Overview of Gene therapy

TOTAL : 45 PERIODS

TEXTS/REFERENCES

1. Primrose S.B., Twyman R.H., and Old R.W. "Principles of Gene Manipulation". 6th Edition., Blackwell Science, 2001
2. Winnacker E.L. "From Genes to clones: Introduction to Gene Technology". Panima,2003
3. Glick B.R. and Pasternak J.J. "Molecular Biotechnology: Principles and applications ofrecombinant DNA" 3rd Edition., ASM Press, 2003.
4. Lemonie, N. R. and Cooper, D.N. Gene Therapy, BIOS, 1996.

BP7111	FORMULATION AND ANALYTICAL TECHNIQUES IN BIOPHARMACEUTICAL TECHNOLOGY	L	T	P	C
		0	0	6	3

OBJECTIVES

This course will provide hands on experience on different forms of drug formulation and theanalytical methods available for evaluation of pharmaceuticals.

OUTCOME

Hands on experience to make the students competent in drug formulation to taken upchallenging industry career.

PART I: FORMULATION EXPERIMENTS

1. Preparation of solid dosage forms (Eg. Granules, Tablets, Capsules)

2. Preparation of liquid dosage forms (Eg. True Solutions, mixtures, Elixers)

3. Preparation of biphasic dosage forms (Eg. Emulsion, Suspension)

4. Preparation of semisolid dosage forms (Eg. Ointments, Creams, Gels, lotions)

5. Preparation of Parenteral and ophthalmic formulations

6. Preparation of specialized dosage forms (Eg. Suppositories, Patches)

PART – II: ANALYTICAL METHODS FOR EVALUATION OF PHARMACEUTICALS BASEDON PHARMACOPOEIAS

1. Evaluation of solid dosage forms (Hardness, dissolution etc)

2. Evaluation of liquid dosage forms (Stability tests, pH, odouretc)

3. Evaluation of biphasic dosage forms (Stability tests etc)

4. Evaluation of semisolid dosage forms (pH, spreadability, viscosity etc)

5. Evaluation of Parenteral formulations and evaluation (Microbial Tests etc)

6. Evaluation of specialized dosage forms (Melting tests etc)

7. Preparation of pharmaceutical buffers and determination of buffer capacity, physiologicalbuffers.

EQUIPMENTS REQUIRED

1. Mortar and Pestle
2. Sieves of all sizes
3. Granulator
4. Punching machine
5. Capsule filler
6. Disintegration, dissolution and friability testing apparatus
7. Formulation reagents (surface acting agents, glidants, diluents etc,)
8. pH meter, physical balances

TOTAL : 90 PERIODS

TEXTS/REFERENCE

1. Lachman, Leon etal., "The Theory and Practice of Industrial Pharmacy", 3rd Edition, Varghese Publishing House, 1986.
2. Ansel, H.C. "Pharmaceutical Dosage Forms and Drug Delivery Systems", 7th Edition, Lippincott Williams & Wilkins, 2000.
3. Lieberman, H.A. etal., "Pharmaceutical Dosage Forms : Tablets" (Vol. I, II & III)2ndEdition, Marcel Dekkar, 1989.
4. Lieberman, H.A. etal., "Pharmaceutical Dosage Forms: Disperse Systems" (Vol.I,II& III)2nd Rev. Edition, Marcel Dekker, 1996.
5. Avis, K.E. etal., "Pharmaceutical Dosage Forms: Pareutal Medications", (Vol.I, II &III)2nd Rev. Edition, Marcek Dekker, 1992

BP7201 DRUG DOSAGE FORMS AND DESIGN

L	T	P	C
3	0	0	3

OBJECTIVES

To enable students to acquire theoretical knowledge in pharmaceutical dosage forms andunderstanding the theoretical principles with application oriented problems.

OUTCOME

The students would have learnt various dosage forms of drugs, technological advancementsto improve formulations at the completion of course.

UNIT I INTRODUCTION TO DOSAGE FORMS 5

History & Evolution; Definitions and Classification of Dosage forms and routes ofAdministration (Oral, Parenteral, Topical, Rectal and Nasal), Pharmacokinetics/Pharmacodynamics parameters for Dosage form development

UNIT II PREFORMULATION AND STABILITY STUDIES 9

Physical properties of drugs - physical form, polymorphism, particle size, shape, density,wetting, dielectric constant, solubility, dissolution, organoleptic property and their effect onformulation, stability and bioavailability. Study of chemical properties of drugs like hydrolysis,oxidation, reduction, racemization, polymerization, etc. and their influence on formulationand stability of products. Stabilization and stability testing protocol for variouspharmaceutical products.

UNIT III SOLID DOSAGE FORMS 9

Capsules: Materials f or production of hard/Soft gelatin capsules, size of capsules andmethod of capsule filling. Importance of base absorption, manufacturing, quality control, stability and storage of capsule dosage forms. Micro-encapsulation- Classification, Methodsof preparation and Evaluation of microcapsules. Tablets : Classification, tablet excipients,Mixing; Milling; Drying; Compression; Coating; Filling; Sealing; Solubility; Filtration,Clarification, Sieving; granulation technology, tablet compression and machinery, processingproblems and evaluation. Coating- Types, materials for coating, formulation, equipment's,film defects and evaluation of coated tablets.

UNIT IV LIQUID, SEMI-SOLID AND AEROSOL DOSAGE FORMS 12

Liquid Dosage forms: Additives in formulations, vehicles, stabilizers, preservatives,suspending agents, emulsifying agents, solubiliser, colors, flavors, manufacturing,packaging and evaluation of clear liquids, suspensions and emulsions official inpharmacopoeia.Semisolid Dosage Forms: Mechanisms of drug penetration, factors influencing penetration,semisolid bases and their selection. General formulation of semisolids, clear gels,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 V PARENTERALS AND ADVANCED/NOVEL DRUG DELIVERY SYSTEMS 10

Parenteral; Liquids,(Solutions, Suspensions, Emulsions); Nasal; Ophthalmic and OpticPreparations; Packaging biopharmaceutical dosage design & delivery.

Sustained release and controlled release Pharmaceuticals – Classification andconstruction of products and evaluation. Novel Drug delivery systems – Transdermaldelivery systems, Osmotic drug delivery systems, Liposomes, Nanoparticles.

TOTAL : 45 PERIODS

TEXTS/REFERENCES

1. Ansel, H.C. "Pharmaceutical Dosage Forms and Drug Delivery Systems", 7th Edition,Lippincott Williams & Wilkins, 2000.
2. Tipnis, H.P. "Bioavailability and Bioequivalence: An Update". New Age International,1996.
3. Lieberman, H.A. "Pharmaceutical Dosage Forms: Tablets". Vol.1-3, 2nd Edition, MarcelDekker, 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, Willaims& Wilkins, 2004.

BP7202 DRUG REGULATORY, QUALITY AND SAFETY EVALUATION L T P C
3 0 0 3

OBJECTIVES

To enable students to acquire knowledge in drug regulatory affairs in India and atInternational level.

OUTCOME

After completion of the course, students would have learned the principles of drug regulatoryaffairs and latest information on drug research, manufacturing, sales and distribution.

UNIT I INTRODUCTION AND DRUGS & COSMETIC ACT 8

Definitions, Forms, Licenses; Schedules, New Schedule M, Schedule Y

UNIT II PHARMACOPOEIA 6

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

UNIT III CGMPS& REGULATORY RECORDS-SITE MASTER FILE, DRUGMASTER FILE, DRUG DOSSIERS 10

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, JapanesePMDA. Drug dossier contents - CTD (CMC section) & data

UNIT IV CLINICAL STUDIES- PRECLINICAL, PHASE I,II,III,IV 6

Schedule-Y, pre-clinical study requirements, clinical trial phases, types of trials, bioethics &stakeholders, Bioavailability & Bio equivalence studies,

UNIT V SAFETY AND ENVIRONMENTAL CONTROL 15

Patent act- Patent, Trade Mark Regn, I.P.R; Saf9ety & Environmental control; Project(Regulatory Factors).

TOTAL : 45 PERIODS

TEXTS/REFERENCES

1. Abraham, John and Smith, H.W. "Regulation of the Pharmaceutical Industry", Palgrave,Macmillan, 2003.
2. Weinberg, Sandy "Good Laboratory Practice Regulations" 3rdEdition, Marcel Dekker,2003.
3. Gad, Shayne C. "Drug Safety Evaluation", Wiley-Interscience, 2002
4. Malik, Vijay "Drugs and Cosmetics Act, 1940". EBC Publishing Co, 1998.
5. "Quality Assurance ofPharamceuticals: A Compendium of Guidelines and RelatedMaterials", Vol.I& II, World Health Organization and Pharma Syndicate, 2002.
6. Berry, Ira R. and Harpaz, Daniel "Validation of Active Pharmaceutical Ingredients", 2ndEdition, CRC Press, 2001
7. British Pharmacopiea
8. United States Pharmacopoiea

BP7204 IMMUNOPHARMACOLOGY L T P C
3 0 0 3

OBJECTIVES

To enhance theoretical knowledge in the function of immune system in humans and tounderstand the applications of immunology and drug response .

OUTCOME

On completion of course students will learn advanced knowledge inpharmacology of drugs

acting on the immune system, their classification, therapeutic use,mechanism of action; their utility in the treatment of inflammatory disease states and life-style diseases and identification of novel therapeutic targets for their treatments; therelationship of immuno therapeutics with other drugs and their role in the modulation of thebody's own natural defenses.

UNIT I INTRODUCTION TOPHARMACOLOGY AND IMMUNOLOGY 9

Principles of basic and clinical pharmacokinetics and pharmacodynamics. Adverse drugreactions. Drug interactions, Bioassay of drugs and biological standardization of immuno-agents, Immune cell and organ classification, Relationships between immune andneurohumoral regulations, influence of stress, nutrition and environment on immunity;Overview of drug discovery and development of immuno-drugs.

UNIT II INTRODUCTION TO VACCINOLOGY 9

Classification, active immunization, vaccines technology, perspective vaccines, means ofpassive immunization, antibodies in therapy, antibody engineering, monoclonal antibodies,immunoconjugates - specific drug targeting, immunotoxins.

UNIT III IMMUNO THERAPEUTICS 9

Cytokines classification, pathways of activation, Therapeutic use of cytokines,immunomodulators classification, thymic hormones and synthetic immunostimulators;compliment pathways diagnostics, development of immuno diagnostics, ELISA, Flowcytometry, ELISPOT,immnuno radiology, Basic immunotoxicology - principles of testing ofimmunomodulating and immunotoxicological properties of drugs and xenobiotics.

UNIT IV TRANSPLANTATION THERAPEUTICS 9

Laws of transplantation, host vs. Graft and graft vs. Host reactions; HLA classificationimmunosuppressants, drugs for immunosupressive therapy: corticosteroids, antimetabolitesand calcineurine inhibitors, Clinical aspects of antiallergic, immunosuppressive,immunostimulating and substitutive therapy.

UNIT V IMMUNOLOGY OF ALLERGY 9

Classification of hypersensitivity reactions, Classification of allergens, therapy andprevention of allergic diseases and drug hypersensitivity. Classification of antihistamines,anti-rheumatoid drugs.

TOTAL : 45 PERIODS

TEXT BOOKS

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" 7 th Edition, Elsevier.2006
3. Mycek M.J., Gerlnet S.B and Perper M.M. "Lippincott's Illustrated PharmacologyReviews",Lipincott Company, Philadelphia.

REFERENCES

1. Goodman and Gilman's, "The Pharmacological Basis of Therapeutics".
2. Katzung, B.G., "Basic and Clinical Pharmacology", Prentice Hall International

Attested

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BP7203 **FERMENTATION TECHNOLOGY** **L T P C**
3 0 0 3

OBJECTIVE

The subject provides knowledge involving basic principle of fermentation process, microbialkinetics and recombinant protein production along with case studies, to help the studentsunderstand fermentation processes involved in Pharmaceutical Industries.

OUTCOME

This course work will provide essential knowledge f or the students to make their career inbioprocess Industries.

UNIT I INTRODUCTION TO BIOREACTOR DESIGN & CONSTRUCTION 9

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

UNIT II MICROBIAL KINETICS AND DESIGN OF VARIOUS CULTIVATIONPROCESSES 9

Simple unstructured kinetic models for microbial growth of bacterial, fungal, animal and plantsystems, kinetics of substrate utilization, biomass growth and product formation incontinuous cultures, batch and fed batch cultures, total cell retention cultivation, inhibition oncell growth and product formation.

UNIT III MODELING OF RECOMBINANT CULTIVATION SYSTEMS 9

Structured models of metabolism and growth, models of gene expression and regulation, ageneralized model of plasmid replication, Genetic instability, predicting host-vectorinteractions and genetically instability. Process considerations for utilizing geneticallyengineered strains.

UNIT IV ANIMAL AND PLANT CELL CULTIVATION TECHNOLOGY FORTHERAPEUTIC PROTEINS 9

Media,aeration in cell culture systems,Bioreactors for plant/animal suspension culture, cellimmobilization and organized tissue, bioreactor considerations for animal /plant cell culturefor production of pharmaceuticals,Therapeutic proteins and Monoclonal antibodies.

UNIT V CASE STUDIES IN FERMENTATION DERIVED PRODUCTS 9

Case studies on Production of penicillin, recombinant Insulin. Case studies should deal withstrain improvement, medium design, reactor design & process optimization etc.

TOTAL : 45 PERIODS

TEXTS BOOKS

1. Shuler, M.L. and Kargi, F. "Bioprocess Engineering: Basic Concepts". 2nd Edition,Prentice- Hall, 2002.
2. Doran, Pauline M, "Bioprocess Engineering Principles". Academic Press, 1995
3. Nielsen, J. and Villadsen, J. "Bioreaction Engineering Principles". Springer, 2007.
4. Blanch, H.W and Clark D.S., "Biochemical Engineering", Marcel Dekker,1997

REFERENCES

1. Bailey, J.E. and Ollis, D.F. "Biochemical Engineering Fundamentals" 2nd Edition.,McGraw Hill, 1986.
2. Stanbury, Stephen. P. F., Hall, J. and Whitaker, A. "Principles of FermentationTechnology" Elsevier

BP7211	IMMUNOPHARMACOLOGY LAB	L	T	P	C
		0	0	6	3

OBJECTIVES

The student will undergo hands on experience on animal handing and various aspects ofadvanced immunological techniques like Competitive ELISA, Immunoprecipitations and Flowcytometry assays. The students will undergo invitro immuno assays training.

OUTCOME

Students are expected to absorb the principles and practical approach of modernimmunological techniques required for both industry and academic research.

1. Selection and Handling of animals, Preparation of antigens, Immunization andmethods of bleeding, Serum separation, Storage.
2. Antibody titre by ELISA method (Direct ELISA)
3. Competitive ELISA – Quantification of antigens
4. Cytokine analysis by Elispot test
5. Immunoprecipitation / Immunoelectrophoresis
6. Isolation and purification of IgG from serum
7. SDS -PAGE, Immunoblotting, Dot blot assays
8. Demonstration of agglutination inhibition by latex beads (Pregnancy test)
9. Direct Agglutination – Widal test Salmonella detection
10. Separation of mononuclear cells by Ficoll-Hypaque
11. Separation and culturing of spleenocytes and demonstration of T cell proliferation
12. Lymphoproliferation by mitogen/antigen and Thymidine uptake assay
13. Demonstration of cell viability by MTT assay
14. Flowcytometry, identification of T cells and their subsets
15. Evaluation of monoclonal antibodies for diagnostic and therapeutic applications
16. Demonstration of Immunodiagnostics using commercial kits (Rapid Dot Blot and StripTest)

TOTAL : 90 PERIODS

TEXTS/REFERENCES

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

BP7311	DRUG DISCOVERY LAB	L	T	P	C
		0	0	6	3

OBJECTIVES

To enable the students to enhance their hands-on experience in learning techniquestowards discovery of new drugs and utilize this knowledge for industrial needs.

OUTCOME

The Students will be able to absorb the principles and practical approach of modern drugdiscovery including synthetic methods and natural products f or drug discovery as perindustry standards.

SYNTHETIC METHODS FOR DRUG DISCOVERY

1. Synthesis of selected drugs involving two or more steps of synthesis and study of spectralanalysis of drug synthesized (Paracetamol,Aspirin, Fluorscein, acetanilide, etc.).
2. Determination of pharmacopoeial standards for the synthesized drugs.
3. Determination of QSAR parameters for drugs (partition co-efficient, dissociation constant,molar refractivity, etc.)

DISCOVERY OF DRUGS FROM NATURAL PRODUCTS

1. Extraction Techniques: Cold maceration, Hot Percolation and Soxhalation.
2. Evaluation of extraction Effeciency by yield calculation and TLC.
3. Fractionation : Solvent-solvent
4. Evaluation of fractionation effeciency by TLC fingerprinting.
5. Column chromatography and flash column chromatography.
6. Extraction and determination of alkaloids (caffeine acid from tea leaves).
7. To evaluate the antioxidant potential of herbal extracts using DPPH free radicalscavenging assay.
8. To evaluate the cytotoxic effect of herbal extracts using MTT assay.
9. To evaluate the nitric oxide (NO) modulatory effect of herbal extracts using Griessmethod.
10. Biotransformation study

TOTAL : 90 PERIODS

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TEXTS/REFERENCES

1. Foye's Principles of Medicinal Chemistry. By David A. Williams, Thomas L.Lemke, Thomas L. Lernke, William O. Foye. Lippincott Williams & Wilkins Publishers; 5th edition
2. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry. ByJaime N. Delgado (Editor), Ole Gisvold (Editor), William A. Remers (Editor). LippincottWilliams & Wilkins Publishers; 10th edition (August 1998) ISBN: 0397515839
3. Remington: The Science and Practice of Pharmacy
4. Modern methods of plant analysis – Peech and M. V. Tracey
5. PhytochemistryVol I & II by Miller, Jan, Nostrant, Rein Hid
6. Recent advances in Phytochemistry Vol. I & IV – Scilicet, Runeckles
7. Natural Product Chemistry "A laboratory guide" by RaphealIkan.

BP7312	PROJECT WORK – PHASE I	L	T	P	C
		0	0	12	6

OBJECTIVES

To provide research training in areas of Biopharmaceutical Technology and to stimulate thestudents to undertake research in this area.

OUTCOME

Students would have developed expertise one or two techniques pertaining to one or twotechniques pertaining to research in biopharmaceutical technology and would be able toperform literature survey and make a comprehensive report presentation in a specified area.

BP7411	PROJECT WORK – PHASE II	L	T	P	C
		0	0	24	12

OBJECTIVES

To provide research training in specific areas of Biopharmaceutical Technology and todevelop their skills for academic and industrial research.

OUTCOME

The students will be trained to undertake cutting edge research in the area ofBiopharmaceutical Technology.

BP7071	PHARMACOGENOMICS	L	T	P	C
		3	0	0	3

OBJECTIVES

The course intends to provide knowledge about Pharmacogenomics and drug design usinggenomic applications for drug action and toxicity.

OUTCOME

At the completion of course, the student would have learnt advanced pharmacogenomicsenabling him for cutting edge academic and industrial research.

UNIT I INTRODUCTION TO PHARMACOGENOMICS 9

Pharmacogenetics-The roots of pharmacogenomics, It is not just pharmacogenomics,Genetic drug response profiles, the effect of drugs on Gene expression, pharmacogenomicsin 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, Genomicdifferences that affect the outcome of host pathogen interactions: A template for the future ofwhole genome-based pharmacological science.

UNIT III ASSOCIATION STUDIES IN PHARMACOGENOMICS 9

Viability and ADR in drug response: contribution of genetic factor, Multiple inherited geneticfactors 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 ofpharmaceutical industry, Understanding biology and diseases, Target identification andvalidation, 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-thescale of problem, Mutation of drug target s leading to change in the ligand binding pocket.

TOTAL : 45 PERIODS

TEXTS/REFERENCE

1. Licinio, Julio and Ma-Li Wong, “Pharmacogenomics: The Search for the IndividualizedTherapies”, Wiley-VCH, 2002
2. Chabrabarthy, Chiranjb and Bhattacharyya, Atane, “Pharmacogenomics: An Approachto New Drugs Development”, 2004.
3. Othstein, Mark, A. “Pharmacogenomics: Social, Ethical and Clinical Dimensions”, Wiley-Liss, 2003

BT7074 BIOCATALYSTS AND ENZYME TECHNOLOGY

L	T	P	C
3	0	0	3

OBJECTIVES

The course intends to give advanced knowledge about Biocatalysts, Enzyme kinetics,immobilization and enzymatic biotransformation of drugs

OUTCOME

The students will acquire knowledge in all aspect of Biocatalysis, enzyme kinetics andimmobilization. The enzymatic transformationwill give theoretical idea about drugbiotransformation.

UNIT I BASICS OF ENZYMES AS BIOCATALYSIS 9

Introduction to enzymes, Classification, Sources, Mechanism of enzyme action. Strategies ofpurification of enzymes, criteria of purity, molecular weight determination andcharacterization of enzymes , Enzymes of biological importance - Acetylcholinesterase,angiotensin converting enzyme (ACE), ACE Inhibitors, HMG Co A reductase inhibitors,pseudocholinesterase, 5 -nucleotidase (5NT), glucose-6-phosphate dehydrogenase (GPD),CKisoforms, immunoreactivetrypsinogen (IRT) and chymotrypsin; amylase isoenzymes

UNIT II KINETICS OF ENZYME ACTION 9

Methods for investigating the kinetics of Enzyme catalysed reactions – Initial velocityStudies, Estimation of MichaelisMenten parameters, Effect of pH and temperature onenzyme activity, kinetics of inhibition. Modeling of rate equations for single and multiplesubstrate reactions.

UNIT III IMMOBILIZED ENZYMES 9

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

UNIT IV ENZYMES IN FUNCTIONAL GROUP TRANSFORMATION 9

Functional group interconversion using enzyme s (hydrolysis reaction, oxidation/reductionreactions, C-C bond formations), Retrosynthetic biocatalysis, Chemoenzymatic synthesis ofnatural products. Industrial process using enzymes for production of drugs, fine chemicalsand chiral intermediates.

UNIT V ENZYMATIC TRANSFORMATION 9

Reaction engineering for enzyme-catalyzed biotransformations. Catalytic antibodies.Biocatalysts from extreme Thermophilic andHyperthermophilicmicroorganisms(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 andchiral intermediates.

TOTAL : 45 PERIODS

Attested

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TEXTS/REFERENCES

1. Blanch, H.W., Clark, D.S. Biochemical Engineering, Marcel Dekker, 1997
2. Lee, James M. Biochemical Engineering, PHI, USA, 1982.
3. Bailey J.E. &Ollis, D.F. Biochemical Engineering Fundamentals, 2nd Ed., McGraw Hill,1986
4. Faber, Kurt "Biotransformations in organic chemistry: A Textbook" 5thEdition. Springer2008.
5. Enzyme catalysis in organic synthesis (Vol I-III); Eds by K .Drauz and H. Waldmann.Willey-VCH (ISBN: 3-527-29949-1)
6. Hydrolases in organic synthesis (regio and stereoselectivebiotransformations). U. T.Bornscheuer and R. J. Kazlauskas. Willey-VCH. (ISBN: 3-527-30104-6).
7. Stereoselectivebiocatalysis. Ed. R.N. Patel. Marcel Dekker. (ISBN: 0-8247- 8282-8)

BP7003	CLINICAL TRIALS AND BIOETHICS	L	T	P	C
		3	0	0	3

OBJECTIVES

The course will provide Fundamental ethical to Advanced clinical trial management includingdrug development and trial planning; Project management in clinical trials; Consent and dataprotection; Quality assurance and governance.

OUTCOME

The students will acquire knowledge in all aspect of clinical trials, management and ethicalstandards required to conduct clinical trials.

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 theEuropean directives and legislation governing clinical trials in the 21stcentury; Internationalperspectives; 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; Regulatoryapprovals for clinical trials; Consort statement; Trial responsibilities and protocols - roles andresponsibilities of investigators, sponsors and others; Requirements of clinical trialsprotocols; 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 inclinical trial management; Risk assessment; Research ethics and Bioethics - Principles ofresearch ethics; Ethical issues in clinical trials; Use of humans in Scientific Experiments;Ethical committee system including a historical overview; the informed consent; Introductionto ethical codes and conduct; Introduction to animal ethics; Animal rights and use of animalsin the advancement of medical technology; Introduction to laws and regulation regarding useof animals in research.

UNIT IV INFORMED CONSENT **9**

Consent and data protection- the principles of informed consent; Consent processes; Dataprotection; Legislation and its application; Data management – Introduction to trial masterfiles 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-trialclosure; Reporting and legal requirements; Common pitfalls in clinical trial management.

TOTAL : 45 PERIODS

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.

BT7073 ADVANCES IN MOLECULAR PATHOGENESIS **L T P C**
3 0 0 3

OBJECTIVES

The course will proved advanced information on molecular pathogenesis of infectiousdiseases.

OUTCOME

The subject will help the student towards understanding the virulence of the pathogen andHost-parasite interactions for advanced academic and industrial research in molecularpathogenesis.

UNIT I INTRODUCTION **5**

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 DEFENSESTRATEGIES **10**

Skin, mucosa, cilia secretions, physical movements, physical and chemical barriers tobacterial 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 **10**

Virulence, Colonization factors, Microbial toxins, Secretion systems: General secretorypathway,

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Two-step secretion, Contact dependent secretion, Conjugal transfer system andAutotransporters.

UNIT IV MECHANISMS UNDERLYING MOLECULAR PATHOGENESIS 10(COMMON ENTERIC PATHOGENS)

Shigella: Entry, Induction of macropinocytosis, Invasion of epithelial cells, Intracellularmotility and spread, Apoptotic killing of macrophages, Virulence factors involved.***E.coli***:**Enterotoxigenic*E.coli*(ETEC), labile & stable toxins, Entero-pathogenic*E.coli*

(EPEC), typeIII secretion, Cytoskeletal changes, intimate attachment; Enterohaemerrohogic*E.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-ENTE RIC PATHOGENS) 10

Mycobacterium tuberculosis: The Mycobacterial cell envelope, Route of entry, Uptake bymacrophages, Latency and persistence, Entry into and survival in phagocytes, Immuneresponse against MTB, MTB virulence factors, Emergence of resistance.**Influenza virus:**Intracellular stages, Neuraminidase and Haemagglutinin in entry, M1 & M2 proteins inassembly and disassembly, action of amantadine.**Plasmodium:**Lifecycle, erythrocytestages, transport mechanism and processes to support the rapidly growing schizont,parastiparous vacuoles and knob protein transport, Antimalarial based on transportprocesses.

TOTAL : 45 PERIODS

TEXTS/REFERENCES

1. Salyers, Abigail A. “Bacterial Pathogenesis: A Molecular Approach”
2. Groisman, “Principles of Bacterial Pathogenesis”.
3. Waksman, Gabriel and Michael caparon “Structural Biology of Bacterial Pathogenesis”.
4. Clark, Virginia L. “Bacterial Pathogenesis”
5. Williams, Peter “Bacterial Pathogenesis” (Methods in Microbiology)
6. McClane, Bruce A. “Microbial Pathogenesis”
7. Madigan, Michael T. “Biology of Microorganisms”
8. Stanley, “Genetic analysis of Pathogenic Bacteria”.
9. 9. Hacker, Jorg “Molecular Infection Biology”

BT7076 METABOLIC PROCESS AND ENGINEERING

L	T	P	C
3	0	0	3

OBJECTIVES

To familiarize the student with quantitative approaches for analyzing cellular metabolism andthe use of theoretical and experimental tools that can give insights into the structure andregulation of metabolic networks. A central aspect of the course is to identify the optimalstrategy for introducing directed genetic changes in the microorganisms with the aim ofobtaining better production strains. Case studies will be taken up on metabolically-engineered products and processes in various expression systems.

OUTCOME

This course work will provide essential knowledge for the students to make their career inbioprocess Industries.

UNIT I METABOLIC FLUX ANALYSIS 9

Introduction to metabolic engineering, comprehensive models of cellular reactions withstoichiometry and reaction rates; metabolic flux analysis of exactly/over/under determinedsystems. Shadow price, sensitivity analysis.

UNIT II TOOLS FOR EXPERIMENTALLY DETERMINING FLUX THROUGHPATHWAY 9

Monitoring and measuring the metabolome, Methods for the experimental determination ofmetabolic fluxes by isotope labeling metabolic fluxes using various separation –analyticaltechniques. GC-MS for metabolic flux analysis, genome wide technologies: DNA /phenotypicmicroarrays and proteomics.

UNIT III CONSTRAINT BASED GENOMIC SCALE METABOLIC MODEL 9

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

UNIT IV METABOLIC CONTROL ANALYSIS AND KINETIC MODELING 9

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

UNIT V CASE STUDIES IN METABOLIC ENGINEERING 9

Metabolic engineering examples for bio-fuel, bio-plastic and green chemical synthesis. Studyof genome scale model in various systems

for the production of green chemicals usingsoftware tools. Validation of the model with experimental parameters.

TOTAL : 45 PERIODS

TEXT BOOKS

1. Stephanopoulos, G.N. “Metabolic Engineering: Principles and Methodologies”. AcademicPress / 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, 2010.

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REFERENCES

1. Voit, E.O. “Computational Analysis of Biochemical Systems: A Practical Guide forBiochemists and Molecular
2. Biologists”. Cambridge University Press, 2000.
3. Scheper, T. “Metabolic Engineering” Vol 73 (Advances in Biochemical EngineeringBiotechnology) Springer, 2001.
4. Cortassa, S. et al, “ An Introduction to Metabolic and Cellular Engineering”, WorldScientific Publishing, 2002.
5. Kholodenko, Boris N and H. V. Westerhoff “Metabolic Engineering in the Post GenomicEra”, Horizon Bioscience, 2004.

BT7075 COMMUNICATION SKILL DEVELOPMENT

L	T	P	C
3	0	0	3

OBJECTIVES

To enhance the overall capability of students and to equip them with the necessarycommunication and soft skills to enable them to excel in their profession

OUTCOME

The course will enhance soft skills and interpersonal skills, which will make their transitionfrom college to work place smoother and help them excel in their job.

UNIT I PROCESS OF COMMUNICATION 9

Concept of effective communication- Setting clear goals for communication; Determiningoutcomes and results; Initiating communication; Avoiding breakdowns while communicating;Creating value in conversation; Barriers to effective communication; Nonverbalcommunication- Interpreting nonverbal cues; Importance of body language, Power ofeffective listening; recognizing cultural differences

UNIT II PRESENTATION SKILLS 9

Formal presentation skills; Preparing and presenting using Over Head Projector, PowerPoint; Defending Interrogation; Scientific poster preparation & presentation; Participating ingroup discussions

UNIT III TECHNICAL WRITING SKILLS 9

Types of reports; Layout of a formal report; Scientific writing skills: Importance ofcommunicating Science; Problems while writing a scientific document; Plagiarism; ScientificPublication Writing: Elements of a Scientific paper including Abstract, Introduction,Materials& Methods, Results, Discussion, References; Drafting titles and framing abstracts

UNIT IV COMPUTING SKILLS FOR SCIENTIFIC RESEARCH 9

Web browsing for information search; search engines and their mechanism of searching;Hidden Web and its importance in Scientific research; Internet as a medium of interactionbetween scientists; Effective email strategy using the right tone and conciseness

UNIT V RESUME / REPORT PREPARATION / LETTER WRITING 9

Students prepare their own resume and report, Presentation- Students make presentationson given topics, Group Discussion- Students participate in group discussions, and InterviewSkills- Students participate in Mock Interviews

TOTAL : 45 PERIODS

TEXTS/REFERENCES

1. Mohan Krishna and N.P. Singh, Speaking English effectively, Macmillan, 2003.

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BP7002	CHEMISTRY OF NATURAL PRODUCTS	L	T	P	C
		3	0	0	3

OBJECTIVES

To enhance theoretical knowledge of students in the chemistry of natural products and toexplore this knowledge for practical applications

OUTCOME

At end of the course work students will appreciate the importance of natural compounds asnovel drug entity for the development of newer drugs.

UNIT I CARBOHYDRATES AND RELATED COMPOUNDS 9

Sugars and sugar – containing drugs polysaccharides and polysaccharide –containing drugscellulose 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, isothiocyanateflavonollactone glycosides tannins volatile oils, resins and resin combinations.

UNIT III ALKALOIDS AND ALICYCLIC COMPOUNDS 9

Pyridine and piperidine alkaloids, Tropane alkaloids, Quinolinealkaoids, isoquinolinealkaloids, Indole alkaloids, Imidazole alkaloids, Steroidal alkaloids, Alkaloidal amines purinebases. Terpenes, camphor, menthol, carotenes

UNIT IV VITAMINS, PURINES, FLAVONOIDS 9

Chemistry, medicinal and pharmaceutical uses of vitamin A, D, E, K, B_1, B_2, B_6, $B_{12}$and Folicacid. Chemistry and structural elucidation of uric acid, interrelation between caffeine,theophylline and theobromine. Classification and application of f lavanoids (hespiridineetc)

UNIT V MOLECULES FROM NATURAL SOURCES 9

Classification of Drug molecules of Plant/marine/microbial and animal sources-cytotoxic/antineoplastic agents, cardio vascular drugs -antimicrobial substances – anti-inflammatory andantispasmodic agents

TOTAL : 45 PERIODS

TEXTS/REFERENCES

1. Evans, W.C., 'Trease and Evans Pharmacognosy', 15th Edition, Saunders, 2002
2. Wallis, T.E. "Textbook of Pharmacognosy", 5th Edition, CBS Publishers, 2005.
3. Kokate, C.K. "Pharmacognosy", 29th Edition, NiraliPrakashan, 2004.

BT7078	RESEARCH AND RESEARCH METHODOLOGY IN BIOTECHNOLOGY	L	T	P	C
		3	0	0	3

OBJECTIVES

The course will provide knowledge about the objectives to perform research and forinterpretation of data from experimental results and presenting technical publications.

OUTCOME

After the completion of course, students will able to design, conduct, and interpret researchoutcomes for academic and industrial research needs.

UNIT I RESEARCH AND ITS METHODOLOGIES (WITH EXAMPLES) 9

Objectives of research; research process – observation, analysis, inference, hypothesis,axiom, theory, experimentation; Types of research (basic, applied, qualitative, quantitative,analytical etc); Features of translational research, the concept of laboratory to market (benchto public) and Industrial R&D.

UNIT II RESEARCH IN BIOTECHNOLOGY – AN OVERVIEW 9

Biological systems and their characteristics that influence the type and outcome of research;Exploratory and product-oriented research in various fields of biotechnology (health, agri,food, industrial etc). Types of expertise and facilities required; Interdisciplinary nature ofbiotech research; Sources of literature for biotech research

UNIT III EXPERIMENTAL RESEARCH: BASIC CONCEPTS IN DESIGN ANDMETHODOLOGY 9

Precision, accuracy, sensitivity and specificity; major experimental variables, biochemicalmeasurements, types of measurements, enzymes and enzymatic analysis, antibodies andimmunoassays, instrumental methods, bioinformatics and computation, experimental

planning – general guidelines

UNIT IV RESULTS AND ANALYSIS 9

Importance and scientific methodology in recording results, importance of negative results,different ways of recording, industrial requirement, artifacts versus true results, types ofanalysis (analytical, objective, subjective) and cross verification, correlation with publishedresults, discussion, outcome as new idea, hypothesis, concept, theory, model etc.

UNIT V SCIENTIFIC AND TECHNICAL PUBLICATION 9

Different types of scientific and technical publications in the area of biotechnology, and theirspecifications, Ways to protect intellectual property – Patents, technical writing skills,definition and importance of impact factor and citation index; Assignment in technical writing

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TOTAL : 45 PERIODS

TEXT/REFERENCES

1. Essentials of Research Design and Methodology Geoff rey R. Marczyk, David DeMatteo,David Festinger, 2005 John Wiley & Sons Publishers, Inc
2. Biochemical Calculations: How to Solve Mathematical Problems in General
3. Biochemistry, 2nd Edition, Irwin H. Segel, 1976 John Wiley & Sons Publishers, Inc
4. Guide to Publishing a Scientific paper, Ann M. Korner, 2004, Bioscript Press

BP7005	MOLECULAR MEDICINE AND MECHANISM	L	T	P	C
		3	0	0	3

OBJECTIVES

The objective of the course is to understand the molecular mechanism of the disease andadvanced understanding of drug interactions.

OUTCOME

Students will be trained to understand the applications of mechanism of molecular diseases.

UNIT I INTRODUCTION TO MOLECULAR MEDICINE 9

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

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

UNIT II CARDIOLOGY 9

Molecular Cardiology – Congenital Heart Disease – Inherited Cardiomyopathies – CoronaryAtherosclerosis – 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 NeoplasiaGrowth Hormone Deficiency Disorders – Thyroid Disorders – Disorders of the parathyroidGland – Congenital Adrenal Hyperplasia – Adrenal Disease – Multiple Endocrine NeoplasiaType 2 – Molecular Mechanisms of Hypoglycemia Associated with increased InsulinProduction.

UNIT V NEPHROLOGY **9**

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

TOTAL : 45 PERIODS

TEXTS/REFERENCES

1. Jameson, J. L., Francis, S.C., "Principles of Molecular Medicine", Humand 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", 2ndEdition, Wiley Liss,2005
5. Strachan, Tom and Andrew P. Read. "Human Molecular Genetics, Bios, 1996

BP7004	**CONVENTIONAL AND RATIONAL DRUG DISCOVERY STRATEGIES**	**L**	**T**	**P**	**C**
		3	**0**	**0**	**3**

OBJECTIVES

This subject will expose the students to various principles and methodologies involved in the drug discovery and validation process.

OUTCOME

On the completion of the course the students will learn various conventional and advanced methods employed in newdrug discovery process that will enable them for academic and industry research in future.

UNIT I FUNDAMENTALS ONRATIONAL DRUG DESIGN **9**

Various approaches in drugdiscovery process – conventional versus rational, drug targets, lead identification; Principles of ligand chemistry – lead optimization, pharmacophores, bio-isosteres, principles of ligand chemistry such as configuration, conformation, chirality, isosteric replacement; Parameters of ligan design such as –Physiochemical, geometric, conformational, topological, partitional, steric, stereochemicaland electronic properties of drug molecules; Pharmacokinetic parameters of ligand design such as - lipinski "rule of 5", partition coefficient, hammetcontant, hansch analysis. biological,chemical and physical descriptors used in qsar and qspr. statistical methods used foranalysing 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 bindingfree energy calculations (both simulation and empirical methods), intermolecularinteractions, forces related to drug binding, force-field calculation including solvation, role ofsolubility 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, Selectionand evolution of expression genetic libraries, Combinatorial assembly of antibodygenes, Molecular solutions to Combinatorial problems, Solid-Phase peptide synthesis, Peptide on pins, Other iterative disconvolution 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 analyticalbiochemistry used in HTS (photometry, purification, electrophoresis, kinetic assay,radioisotopes, immunoassay,HTS FACS based assays). Assay design for HTS andstatistical treatment of the results for decision. Introduction to state of the art technologies used in HTS (includingautomated 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

Basic of gene silencing, transgenic worms in drug screening; designing SiRNAs, Types ofRNAi Screens – Loss of Function screens (LOF), Synthetic Lethal screen, Mini-clonogenicRNAi screen; optimizing, and implementing high-throughput siRNA genomic screening forthe discovery of survival genes and novel drug targets, siRNA HTS Screening foridentification 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 arraynormalization.

TOTAL : 45 PERIODS

TEXT BOOKS

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 ScientificPublishers, 2004.
5. Ye, S., and Day, I.N.M. "Microarrays and Microplates: Applications in BiomedicalSciences". BIOS 2003

REFERENCES

1. "Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry".10th Edition, Lippincott-Raven Publisher, 1998.
2. Fassina, G. "Combinatorial Chemistry and Technologies: Methods and Applications", 2nd Edition, CRC Press, 2005
3. Block J.H. and Beale, J.M., 'Wilson &Gisvolds Text book of Organic Medicinal and Pharmaceutical Chemistry', 11th Edition, Lippincott Williams & Wilkins, 2004
4. Janzen W. P. "High Throughput Screening : Methods and protocols". Humana Press. 2002

Attested

DIRECTOR
Centre For Academic Courses
Anna University, Chennai-600 025.

BP7001 BIOCONJUGATE TECHNOLOGY AND APPLICATIONS

L	T	P	C
3	0	0	3

OBJECTIVES

The course will provide advanced theoretical knowledge on Bio conjugate technologies inBiopharmaceutical Applications

OUTCOME

The students will acquire knowledge in advanced methods to carry out cutting edgeacademic and industrial research.

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 – carboxylate reactivechemical reactions – hydroxyl reactive chemical reactions – aldehyde and ketone reactivechemical reactions – Photoreactive chemical reactions.

UNIT III BIOCONJUGATE REAGENTS **9**

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

UNIT IV ENZYME AND NUCLEIC ACID MODIFICATION AND CONJUGATION **9**

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

UNIT V BIOCONJUGATE APLICATIONS **9**

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

TOTAL : 45 PERIODS

TEXT/REFERENCE

1. Hermanson, G.T. “Bioconjugate Techniques”. Academic Press

BT7077	NANOBIOTECHNOLOGY	L	T	P	C
		2	0	2	3

OBJECTIVES

The 'Nanobiotechnology' course aims to provide fundamental concepts of nanotechnologyand advanced knowledge on the application of nanotechnology to biological sciencesincluding nanomedicine.

OUTCOMES

The students would have learned the physicochemical properties of nanomaterials; theunique changes that happen at nanoscale; nanoscale view of the natural biomolecularprocesses; synthesis, modification, and characterization of naomaterials; and application of

Naomaterials to biological problems including nanomedicine.

UNIT I NANOSCALE AND NANOBIOTECHNOLOGY 12

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

UNIT II FABRICATION AND CHARACTERIZATION OF NANOMATERIALS 12

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 filmdeposition; Electrospinning. Bio-synthesis of nanomaterials.

UNIT III PROPERTIES AND MEASUREMENT OF NANOMATERIALS 12

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

UNIT IV NANOBIOLOGY AND BIOCONJUGATION OF NANOMATERIALS 12

Properties of DNA and motor proteins; Lessons from nature on making nanodevices;Reactive groups on biomolecules (DNA & Proteins); Surface modification and conjugation tonanomaterials. Fabrication and application of DNA nanowires; Nanofluidicsto solvebiological problems.

UNIT V NANO DRUG DELIVERY AND NANOMEDICINE 12

Properties of nanocarriers; drug delivery systems used in nanomedicine; EnhancedPermeability and Retention effect; Blood-brain barrier; Active and passive targeting ofdiseased cells; Health and environmental impacts of nanotechnology.

TOTAL : 45 PERIODS

REFERENCES

1. Nanobiotechnology: Concepts, Applications and Perspectives, Christ of M. Niemeyer(Editor), Chad A. Mirkin (Editor) , Wiley-VCH; 1 edition, 2004.
2. NanoBioTechnology: BioInspired Devices and Materials of the Future by OdedShoseyovand Ilan Levy, Humana Press; 1 edition 2007.

3. NanoBiotechnology Protocols (Methods in Molecular Biology) by Sandra J Rosenthaland 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.

BT7071 ADVANCED GENOMICS AND PROTEOMICS

L	T	P	C
3	0	0	3

OBJECTIVES

The course intends to provide advanced theoretical knowledge on the organization and function of genomes, functional genomic analyses, and advanced methods and approaches in proteomics.

OUTCOME

The students will acquire in-depth knowledge on the methods and approaches in genomics and proteomicsareas which help them to carry out cutting edge academic and industrial research.

UNIT I STRUCTURE OF GENOMES, MAPPING AND SEQUENCING 9

Organization and structure of genomes in prokaryotes, eukaryotes, and organelles (chloroplast, mitochondrion); Genome mapping methods (genetic and physical); RAPD, RFLP, SNP analyses; Fluorescence In-Situ Hybridization (FISH) techniques; Advances in gene finding and functional prediction; Chain termination and chemical degradation sequencing methods.

UNIT II LARGE SCALE GENOMICS/ FUNCTIONAL GENOMICS ANALYSES 9

Genome-wide association (GWA) analysis; Comparative Genomic Hybridization (CGH);

Massively parallel Signature Sequencing (MPSS); Whole genome shot-gun sequencing and its applications. Introduction of Next Generation Sequencing (NGS).

UNIT III TRANSCRIPTOMICS ANALYSES 9

Gene expression analysis by cDNA and oligonucleotide arrays; Micro array experimental analysis and data analysis. Methylome analysis using microarray;ChIP-on-Chip analysis. Bioinformatic analysis of large-scale microarray data for comparative transcriptomics.

UNIT IV SEPARATION AND PROCESSING OF PROTEINS FOR PROTEOMICS 9

Over-view of strategies used for the identification and analysis of proteins; Protein extraction from biological samples (Mammalian Tissues, Yeast, Bacteria, and Plant Tissues); 2-DE of proteins for proteome analysis; Liquid chromatography separations in proteomics (Affinity, Ion Exchange, Reversed-phase, and size exclusion); Enzymatic cleavage of proteins. Analysis of complex protein mixtures using Nano-liquid chromatography (Nano-LC) coupled to Mass-spectrometry analysis.

UNIT V MASS SPECTROMETRY AND COMPARATIVE PROTEOMICS 9

Common ionization methods for peptide/protein analysis; Introduction to Mass spectrometers; MALDI-TOF and LC-MS analyses; Comparative proteomics based on global in-vitro and in-vivo labeling of proteins/peptides followed by Mass-spectrometry. Analysis of posttranslational modification (PTM) of proteins; Characterization of protein interactions using yeast two-hybrid system and Protein microarrays; Proteomics informatics and analysis of protein functions.

TOTAL: 45 PERIODS

TEXTS/REFERENCES

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

BT7072 ADVANCED TECHNOLOGIES IN OMICS SCIENCES L T P C
3 0 0 3

UNIT I MICRO ARRAYS IN GENOMICS 9

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

UNIT II NEXT GENERATION SEQUENCING TECHNOLOGIES 9

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

UNIT III PROTEIN MICRO ARRAYS AND YEAST TWO-HYBRID SYSTEM 9

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

UNIT IV TWO-DIMENSIONAL GELELECTRO PHORESIS OF PROTEINS 9

Sample preparation, First-dimension IEF with IPG; Second dimensional separation of

proteins; Image analysis of 2-DE gels; DIGE, Protein expression profiling and comparative proteomics of complex proteomes using 2-DE.

UNIT V MASS-SPECTROMETRY 9

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

TOTAL : 45 PERIODS

REFERENCES

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