

UNIVERSITY DEPARTMENTS
ANNA UNIVERSITY CHENNAI : : CHENNAI 600 025
REGULATIONS - 2009
CURRICULUM I TO IV SEMESTERS (FULL TIME)
M.TECH.BIOPHARMACEUTICAL TECHNOLOGY

SEMESTER – I

SL. NO	COURSE CODE	COURSE TITLE	L	T	P	C
THEORY						
1	BT 9150 BT 9156 BT 9152	Molecular Fundamentals in biology / Fundamentals of chemical engineering / Biogenerics and Biopharmaceuticals	3	0	0	3
2	BT 9111	Biochemical engineering and Fermentation Technology	3	0	0	3
3	BP 9112	Human physiology and drug metabolism	3	0	0	3
4	BP 9113	Medicinal chemistry	3	0	0	3
5		Elective 1	3	0	0	3
6		Elective 2	3	0	0	3
7		Elective 3	3	0	0	3
PRACTICAL						
8	BT 9114	Preparative and analytical techniques in biotechnology	0	0	6	3
TOTAL			21	0	6	24

SEMESTER II

SL.No.	COURSE CODE	COURSE TITLE	L	T	P	C
THEORY						
1	BP 9121	Pharmacological Screening, Assays and biostatistics	3	0	0	3
2	BT 9122	Advanced Genetic Engineering	3	0	0	3
3	BP 9123	Pharmacokinetics and Biopharmaceuticals	2	0	2	3
4	BP 9124	Computational methods in Drug design	2	0	2	3
5		Elective 4	3	0	0	3
6		Elective 5	3	0	0	3
7		Elective 6	3	0	0	3
PRACTICAL						
8	BP 9127	Recombinant DNA and Bioprocess Technology lab	0	0	6	3
Total			19	0	10	24

SEMESTER III

SL. No.	COURSE CODE	COURSE TITLE	L	T	P	C
THEORY						
1	BP 9131	Medicinal chemistry and Drug Discovery lab	0	0	6	3
2	BP 9132	Immunotechnology Lab	0	0	6	3
3	BP 9135	Mini Project	0	0	12	6
TOTAL			0	0	24	12

SEMESTER IV

SL. No.	COURSE CODE	COURSE TITLE	L	T	P	C
1	BP 9141	Project Work	0	0	24	12
TOTAL			0	0	24	12

ELECTIVES SEMESTER I

SL. No.	COURSE CODE	COURSE TITLE	L	T	P	C
1	BT 9153	Applied Mathematics for Biotechnologists	3	0	0	3
2	BP 9158	Advanced Mathematics	3	0	0	3
3	BT 9113	IPR and Biosafety	3	0	0	3
4	BP 9154	Drug Dosage Forms and Design	2	0	2	3
5	BP 9155	Drug regulatory, quality and safety evaluation	3	0	0	3
6	BT 9152	Enzyme technology and Industrial applications	3	0	0	3

ELECTIVES SEMESTER II

SL. No.	COURSE CODE	COURSE TITLE	L	T	P	C
1	BT 9169	Molecular Therapeutics	3	0	0	3
2	BT 9170	Clinical Trials and Bioethics	3	0	0	3
3	BP 9163	Pharmacogenomics	3	0	0	3
4	BT 9171	Advances in Molecular Pathogenesis	3	0	0	3
5	BP 9165	Pharmacognosy	3	0	0	3
6	BP 9166	Molecular Medicine and Modern Genetics	3	0	0	3
7	BT 9160	Bioreactor Engineering	3	0	0	3
8	BP 9168	Combinatorial Methods in Biopharmaceutics	3	0	0	3
9	BP 9169	Nanobiotechnology	2	0	2	3
10	BP 9170	Immunotechnology	3	0	0	3
11	BP 9171	Research and research methodology in biotechnology	3	0	0	3

BT9151**FUNDAMENTALS OF CHEMICAL ENGINEERING****L T P C****3 0 0 3****UNIT I INTRODUCTION****5**

Introduction to chemical engineering sciences and its role in the design & analysis of chemical processes. Overview of unit operations and processes in the chemical industry. Units and conversion factor. Introduction to Dimensional analysis.

UNIT II MATERIAL AND ENERGY BALANCES**13**

Overall and component material balances - Material balances without chemical reactions - Chemical reactions -stoichiometry - conversion and yield - Material balance calculations with chemical reactions – combustion calculations - recycle operations. Energy balances - Entropy - Latent heat - Chemical reactions - combustion. Concepts of chemical thermodynamics, the relation to VLE, solution thermodynamics and reaction thermodynamics.

UNIT III FLUID MECHANICS**9**

Properties of fluids; Fluid statics – forces at fluid surfaces, Pressure and measurement of pressure differences; Fluid flow concepts and basic equations of fluid flow – continuity equation and Bernoulli's equation; shear stress relationship and viscous effects in fluid flow; non newtonian fluids; significance of dimensionless groups in fluid flow operations.

UNIT IV TRANSPORTATION OF FLUIDS**9**

Different types of pumps, compressors and valves. Measurement of fluid flow using hydrodynamic methods, direct displacement method. Types of agitators, flow patterns in agitated vessels, calculation of power consumption – applications in bioreactor design

UNIT V HEAT TRANSFER**9**

Nature of heat flow - Conduction, convection, radiation. Steady state conduction, Principles of heat flow in fluids, Heat transfer by forced convection in laminar and turbulent flow. Heat exchange equipments- principles and design.

TOTAL: 45 PERIODS**TEXT BOOKS AND REFERENCES**

1. Bhatt B.I., Vora S.M. Stoichiometry. 3rd ed., Tata McGraw-Hill, 1977.
2. McCabe W.L., *et al.*, Unit Operations In Chemical Engineering. 6th ed., McGraw-Hill Inc., 2001.
3. Geankoplis C.J. Transport Processes And Unit Operations. 3rd ed., Prentice Hall India, 2003.

BT9156**BIOGENERIC AND BIOPHARMACEUTICALS****L T P C****3 0 0 3****UNIT I BIOGENERIC 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 highselling peptides and proteins; Products with expired patents; Challenging originator's patents; Target products for FOB (follow-on biologicals)/Biosimilars development peptides; Recombinant nonglycosylated 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 IMMUNOGENECITY OF BIOPHARMACEUTICAL 9

Immunogenicity of biopharmaceuticals: Immunogenicity; Factors contributing to immunogenicity (product-related factors, 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

TEXT BOOKS AND REFERENCES

1. Sarfaraz K. Niazi, Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues, CRC Press, 2006.
2. Rodney J Y Ho, MILO Gibaldi, Biotechnology & Biopharmaceuticals Transforming proteins and genes into drugs, 1st Edition, Wiley Liss, 2003.

BT9111 BIOCHEMICAL ENGINEERING AND FERMENTATION TECHNOLOGY L T P C 3 0 0 3

UNIT I INTRODUCTION TO BIOPROCESSES 5

Historical development of bioprocess technology, An overview of traditional and modern applications of biotechnological processes, general requirements of fermentation processes, Basic design and construction of fermentor and ancillaries, Main parameters to be monitored and controlled in fermentation processes.

UNIT II METABOLIC STOICHIOMETRY AND ENERGETICS 8

Stoichiometry of Cell growth and product formation, elemental balances, degrees of reduction of substrate and biomass, available electron balances, yield coefficients of biomass and product formation, maintenance coefficients Energetic analysis of microbial growth and product formation, oxygen consumption and heat evolution in aerobic cultures, thermodynamic efficiency of growth.

UNIT III MEDIA DESIGN FOR FERMENTATION PROCESSES 12

Medium requirements for fermentation processes, Carbon, nitrogen, minerals, vitamins and other complex nutrients, oxygen requirements, medium formulation of optimal growth and product formation, examples of simple and complex media. Medium for plant cell culture and animal cell culture. Medium design of commercial media for industrial fermentations – Plackett burman design, response surface methodology, simplex design, continuous cultivation method to determine the kinetic parameters and maintenance coefficient and pulse & shift method of medium optimization. Case studies on each medium design methods.

UNIT IV KINETICS OF MICROBIAL GROWTH AND PRODUCT FORMATION 10

Phases of cell growth in batch cultures, Fed batch and continuous cultures. Simple unstructured kinetic models for microbial growth, Monod model, Growth of filamentous organisms & yeast. Growth associated (primary) and non-growth associated (secondary) product formation kinetics, Leudeking-Piret models, substrate and product inhibition on cell growth and product formation.

UNIT V FERMENTATION TECHNOLOGY 10

Case studies on production of Lactic acid, Glutamic acid, Pencillin, Microbial Lipase and Protease, Recombinant Insulin. Case studies should deal with strain improvement, medium designs, process optimization etc.,

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Bailey, J.E. and Ollis, D.F. "Biochemical Engineering Fundamentals", 2nd ed., McGraw Hill 1986.
2. Shuler, M.L. and Kargi, F. "Bioprocess Engineering : Basic concepts, 2nd ed., Prentice-Hall, 2002.
3. Doran Pauline M, "Bioprocess Engineering Principles", Academic Press, 1995
4. Stanbury, P.F., Stephen J. Hall & A. Whitaker, "Principles of Fermentation Technology", Science & Technology Books.

**BP9112 HUMAN PHYSIOLOGY AND DRUG METABOLISM L T P C
3 0 0 3**

UNIT I FOUNDATIONS OF PHYSIOLOGY AND OVERALL PHYSIOLOGY CONCEPTS 5

Chemical & Physical Foundations – Homeostatic control – neural & endocrine mechanisms – Transport across cell membranes .ANS, CNS, Cardiovascular system, Gastrointestinal system, Muscle and skeletal system, excretory system

UNIT II GROWTH AND METABOLISM 8
Endocrine control of organic metabolism and growth – reproduction and its endocrine control.

UNIT III DRUG ABSORPTION AND METABOLISM 8
Factors influencing enzyme induction and inhibition; Extraction of drugs; Biliary and fecal excretion; Factors effecting drug metabolism; Drug metabolism in fetus and new born

UNIT IV BIOTRANSFORMATION CONCEPTS 8
Biotransformation of drugs; Enzymes responsible for bio-transformations; Microsomal and non-microsomal, mechanisms.

UNIT V MODEL IN DRUG METABOLISM 8
Models to study drug metabolism; Dose effect relationships; Adverse drug reactions and drug interactions; Toxic reactions; Allergic reactions; Idiosyncrasy; Acute poisoning and its treatment.

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Ganong W.F., 'Review of Medical Physiology', 16th Edition, Prentice Hall, International Inc, USA, 1993
2. Vander A.J., Sherman, J.H. and Luciano, D.S. 'Human Physiology', McGraw-Hill Publishing Company, 1990
3. Carola, R., Harley, J.P. and Noback, C.R., 'Human Anatomy and Physiology', 2nd Edition, McGraw Hill Inc., 1992
4. Guyton, A.C., "Text book of Medical Physiology", 9th Edition, Harcourt Brace & Co., 1996.
5. Ross and Wilson, Human Anatomy and Physiology, ELBS edition. 2007
6. Goodman & Gilman, Laurence L Brunton, The Pharmacological Basis of Therapeutics, 11th Edition, McGraw Hill, New York, 2005.
7. Thomas F. Woolf, Handbook of Drug Metabolism, Marcel Dekker, New York, 1999.

BP9113 MEDICINAL CHEMISTRY L T P C
3 0 0 3

UNIT I 9
Introduction to medicinal chemistry, classification of drugs on the basis of sources, structure, site of action and mode of action, drug metabolism, inactive metabolites, biologically active metabolites, phase I and phase II reactions, prodrugs.

UNIT II 9
Chemistry, Structure property Relationship and properties of drugs having medicinally important heterocyclic compounds such as pyrrol, furan, thiophene, pyridine, pyrimidine, pyrazine, indole, quinoline and Isoquinoline.

UNIT III 9
General properties, chemistry, constitution, biosynthesis, biological action and therapeutic applications of the following.
Alicyclic compounds: Terpenes, camphor, menthol, carotenes.
Alkaloids: Atropine, morphine, codeine, thebaine, reserpine, ephedrine.
Vitamins (water and fat soluble): B1, B2, B6, B12, folic acid, nicotinic acid, biotin, pantothenic acid, ascorbic acid. A, D, E and K.
Hormones: Testosterone, progesterone, estrogen, aldosteron, cortisol, insulin, glucagon, oxytocin and vassopressin.

UNIT IV 9
To study the chemistry, structure, mechanism of action, SAR and therapeutic applications of the following anti microbial drugs

Antibiotics: Penicillins, cephalosporins, streptomycin, chloramphenicol, tetracyclines and erythromycin.

Antimalarial agents: 4-aminoquinolines, 8-aminoquinolines, 9-amino acridines, pyrimidine analogues, mefloquine, cinchona alkaloids.

Anti Tubercular Agents: Ethambutol, isonicotinic acid, hydrazid, rifempacin, thioguanine, cytarabine, 5-fluoracil, dicarbazine.

Antiviral agents: Acyclovir, tromantadine hydrochloride, ribavirin

UNIT V

9

To study the biological targets and drugs including its chemistry, structure, mechanism of action, and structure activity relationship of the following categories

Anti-histaminics, cholinergic drugs, adrenergic drugs, ACE inhibitors, CNS stimulants, tricyclic antidepressants, anti coagulants, anthelmintics, anti neoplastic agents.

TOTAL: 45 PERIODS

TEXTBOOKS AND REFERENCES

1. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry. 10th edition, Lippincott-Raven Publisher, 1998.
2. Nogrady, Thomas, "Medicinal Chemistry: A Biochemical Approach", 2nd Edition, Oxford University Press, 2004.
3. William O. Foye, Thomas L. Lemke and David A. William. Principles of Medicinal Chemistry, 4th edition, 1995.
4. Burger's Medicinal Chemistry and Drug Discovery, edited by E. Wolff, 6th edition, Wiley Interscience, New York, 2003.
5. Hansch C, Sammes P.G. Taylor J.B. Comprehensive Medicinal Chemistry, Pergamon Press, Oxford, 1990.
6. Gurdeep Chatwal, "Organic Chemistry of Natural Products", Vol-II, Third edition, Himalaya Publishing House, 1996.

BT9114

**PREPARATIVE AND ANALYTICAL
TECHNIQUES IN BIOTECHNOLOGY**

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

1. Preparation of Acetate, Tris and Phosphate Buffer systems and validation of Henderson-Hasselbach equation.
2. Reactions of amino acids – Ninhydrin, Pthaldehyde, Dansyl chloride – measurement using colorimetric and fluorimetric methods.
3. Differential estimations of carbohydrates – reducing vs non-reducing, polymeric vs oligomeric, hexose vs pentose
4. Estimation of protein concentration using Lowry's method, Dye-binding method
5. DNA determination by UV-Vis Spectrophotometer – hyperchromic effect
6. Separation of lipids by TLC.
7. Enzyme Kinetics: Direct and indirect assays – determination of K_m , V_{max} and K_{cat} , K_{cat}/K_m
8. Restriction enzyme – Enrichment and unit calculation

9. Ion-exchange Chromatography – Purification of IgG and Albumin
10. Gel filtration – Size based separation of proteins
11. Affinity chromatography – IMAC purification of His-tagged recombinant protein
12. Assessing purity by SDS-PAGE Gel Electrophoresis
13. Chemical modification of proteins – PITC modification of IgG and Protein immobilization

TOTAL: 90 PERIODS

TEXT BOOKS AND REFERENCES

1. Biochemical Methods: A Concise Guide for Students and Researchers, Alfred Pingoud, Claus Urbanke, Jim Hoggett, Albert Jeltsch, 2002 John Wiley & Sons Publishers, Inc,
2. Biochemical Calculations: How to Solve Mathematical Problems in General Biochemistry, 2nd Edition, Irwin H. Segel, 1976 John Wiley & Sons Publishers, Inc,
3. Principles and Techniques of Practical Biochemistry- Wilson, K. and Walker, J. Cambridge Press.

BP9121

**PHARMACOLOGICAL SCREENING
ASSAYS AND BIostatISTICS**

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

UNIT I PRINCIPLES OF SCREENING 9

General principles of screening; Correlations between various animal models and human situations; Animal ethics. Pharmacological screening models for therapeutic areas such as hypertension, cerebral ischaemia, pain, epilepsy, depression, Parkinson's disease, Alzheimer's disease, diabetic, leishmania etc.

UNIT II IN-VITRO AND IN-VIVO SCREENS 9

Correlation between in-vitro and in-vivo screens; Special emphasis on cell-based assay, biochemical assay, radioigand binding assay; High through put screening; High through put pharmacokinetic analysis; Specific use of reference drugs and interpretation of results.

UNIT III ESTIMATION AND HYPOTHESIS TESTING 9

Estimation and Hypothesis testing: Point and interval estimation including fiducial limits; Concepts of hypothesis testing and types of errors; Student-t and Chi square tests; Sample size and power; Experimental design and analysis of variance: Completely randomized, randomized blocks; Latin square and factorial designs; Post- hoc procedures.

UNIT IV CORRELATION AND REGRESSION 9

Correlation and regression: Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient; its statistical significance; Multiple and partial correlations; Linear regression; Regression line; Coefficient of determination; Interval estimation and hypothesis testing for population slope; Introduction to multiple linear regression models; Probit and logit transformations.

UNIT V NON-PARAMETRIC TESTS 9

Non-parametric tests: Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal wallis and Friedman two way anova tests. Spearman rank correlation; Statistical techniques in pharmaceuticals: Experimental design in clinical trials; Parallel and crossover designs; Statistical test for bioequivalence; Dose response studies; Statistical quality control.

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. P.S.S. Sundar Rao, P.H.Richard, J.Richard, An introduction to Biostatistics, Prentice Hall of India(P) Ltd., New Delhi, 2003.
2. Gupta S.P, Statistical Methods, Sultan Chand & Sons, New Delhi, 2005.
3. Jerrold H. Zar, Bio Statistical Analysis, Tan Prints(I) Pvt. Ltd., New Delhi, 2003.
4. Goulden, Methods of Statistical Analysis, Asia Publishing Co., New Delhi, 1962.

**BT9122 ADVANCED GENETIC ENGINEERING L T P C
3 0 0 3**

UNIT I CLONING AND EXPRESSION OF GENES 10

Cloning vehicles, restriction enzymes, restriction modification, linkers, adaptors, homopolymeric trailing, restriction mapping. Expression and purification of recombinant proteins, prokaryotic and eukaryotic expression vectors, in vivo homologous recombination, large scale expression and purification of proteins.

UNIT II LIBRARY CONSTRUCTION 8

cDNA & genomic DNA library construction and screening, preparation of DNA, RNA probes immunoscreening and blotting techniques, etc

UNIT III SEQUENCING 10

Methodology – Chemical & enzymatic, Automated sequence, Genome sequencing methods – top down approach, bottom up approach.

UNIT IV PCR AND MUTAGENESIS 7

PCR principle, applications, different types of PCR, mutagenesis and chmeric protein engineering by PCR, RACE, Kuntels' method of mutagenesis.

UNIT V GENE TRANSFER & GENE THERAPY 10

Introduction of foreign genes into plant and animal cells, creation of transgenic plants and animal knockouts, gene therapy, types and vectors.

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

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

UNIT I DRUG ADMINISTRATION AND BIOAVAILABILITY 10

Definitions, ADME, bioavailability ;Physiology of the absorbing membranes:mechanisms of drug absorption - passive and active transport - Fick's first law - affect of membrane permeability on oral absorption; Factors affecting bioavailability- Physiological, Physicochemical, formulation factors: GI physiology and oral absorption; the physico-chemical factors that affect oral absorption, the pH-partition hypothesis as it applies to drug absorption, drug dissolution; understand formulation factors which affect oral absorption; Routes: oral, sublingual, buccal, parenteral, topical, rectal & inhalation; the pharmacokinetic implications of various routes of administration; the advantages and disadvantage of various routes of administration

UNIT II DRUG DISTRIBUTION, BIOTRANSFORMATION, DRUG EXCRETION &BIOAVAILABILITY 8

The processes by which drugs distribute through the body, volume of distribution, the effect of protein binding on drug distribution processes by which drugs are metabolized, induction and inhibition of metabolism; routes of drug excretion, clearance; Bioequivalence – determination of bioavailability: difference between absolute and relative bioavailability; definition and determination of bioequivalence

UNIT III PHARMACOKINETICS I 10

Compartment models: assumptions made in one compartment models, first order kinetics and linear models, differential equations for a simple pharmacokinetic model; To define, use, and calculate the parameters, k_{el} , $t_{1/2}$, V , and AUC as they apply to a one compartment linear model; Kinetics of IV Bolus administration

UNIT IV PHARMACOKINETICS II 8

Oral administration: Diagrams, schemes, and graphs associated with oral administration, relationship between t_{max} and C_{pmax} ; the Influence of k_a and F on C_p for a given dose; determine k_a using the; method of Residuals; Wagner-Nelson Method; method of Inspection; calculate F using Plasma or Urine Data.

UNIT V PHARMACOKINETIC PHARMACODYNAMIC MODELING 9

Nonlinear pharmacokinetics, Michaelis-Menton kinetics; differential equations associated with nonlinear pharmacokinetic models; the effect of parallel pathways; to estimate the parameters K_m and V_m ; Multiple-dose pharmacokinetics; two-compartment open models; to draw schemes and write differential equations for multicompartment models; to recognize and use integrated equations to calculate pharmacokinetic parameters; metabolite Pharmacokinetics.

Lab:

- 1.One compartment models: - IV Bolus
- 2.One compartment models – Zero-order input
- 3.One compartment models – First-order input
- 4.Computer Applications – Single Dose Simulations
- 5.One Compartment model s- Multiple dosing
- 6.Computer Applications – Multiple dose
- 7.Computer Applications – Two compartment
- 8.Computer Applications – MacDope exercise

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Schoenwald, R.D., "Pharmacokinetics in Drug Discovery and Development", CRC Press, 2002.
2. Notari, R.E., "Biopharmaceutics and Clinical Pharmacokinetics: An Introduction", 4th Edition, Marcell Deckker, 2005
3. Welling, P.G., Francis, L.S. Tse, "Pharmacokinetics Regulatory - Industrial-Academic Perspectives", 2nd Edition, Marcell Deckker, 2005
4. Brahmankar, D.M., "Biopharmaceutical and Pharmacokinetics:A Treatise", Vallabh Prakashan, 1995.

BP9124

COMPUTATIONAL METHODS IN DRUG DESIGN

L T P C

3 0 0 3

UNIT I

9

Configuration, conformation, chirality, rational drug design, various approaches in drug discovery, drug targets, lead identification, lead optimization, pharmacophores, bio-isosteres, isosteric replacement.

UNIT II

9

Physiochemical, geometric, conformational, topological, partitional, steric, stereochemical and electronic properties of drug molecules. To study the SAR and SPR of drugs on modifying size, shape, unsaturation, aromaticity, rigidity, substitutions (alkylation, and halogenation),

UNIT III

9

Lipinski "rule of 5", Partition coefficient, Hammett constant, Hansch analysis. Biological, chemical and physical descriptors used in QSAR and QSPR. Statistical methods used for analysing QSAR/ QSPR data.

UNIT IV

9

Introduction to molecular docking (including methods and scoring functions), de novo pharmacophore elucidation/ drug design for structurally well-defined receptor targets like HIV protease inhibition, ER antagonism, H2 receptor antagonism, Chirase inhibition (quinoline derivative antibiotics) and ACE inhibition, macromolecule-ligand docking, docking algorithms, AUTODOCK

UNIT V

9

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 calculation including solvation, role of solubility in drug binding and pKa, Poisson-Boltzmann Surface Area (PBSA), AMBER, GROMOS and GROMACS

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Williams, D.A. and Lemke, T.L., "Foye's Principles for Medicinal Chemistry: Fifth Edition, Lippincott, Williams & Wilkins, Baltimore, 2002.
2. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry. 10th edition, Lippincott-Raven Publisher, 1998.
3. Alan Hinchliffes, "Modelling Molecular Structures", Second Edition, John Willy & Sons Pvt Ltd, England, 2000.
4. Leach, AR, "Molecular Modeling & Drug Design", Second Edition, John Willy, 2000
5. GROMOS and GROMACS Manuals

BP9127 RECOMBINANT DNA AND BIOPROCESS TECHNOLOGY LAB**L T P C
0 0 6 3**

1. Preparation of plasmid DNA
2. Restriction Digestion of the vector and Insert
3. Ligation and Transformation to *E.coli*
4. PCR for confirmation of the gene
5. Induction experiments in *E.coli* using IPTG, salt etc
6. SDS-PAGE analysis of expression
7. Enzyme kinetics, inhibition, factors affecting reaction ph, temp.
8. Enzyme immobilization studies – Gel entrapment, adsorption and ion exchange immobilisation.
9. Optimization techniques – Plackett burman, Response surface methodology.
10. Batch cultivation – recombinant *E.coli* – growth rate, substrate utilization kinetics, product analysis after induction

TOTAL: 90 PERIODS**BP9131 MEDICINAL CHEMISTRY AND DRUG DISCOVERY LAB****L T P C
0 0 6 3**

1. Extraction Techniques: Cold maceration, Hot Percolation and Soxhalation.
2. Evaluation of extraction Efficiency by yield calculation and TLC.
3. Fractionation : Solvent-solvent
4. Evaluation of fractionation efficiency by TLC fingerprinting.
5. Column chromatography and flash column chromatography.
6. Extraction and determination of alkaloids.
7. Isolation of casein from milk.
8. Isolation of caffeine acid from tea leaves.
9. To estimate the saponification value of castor oil.
HPLC and GC analysis.
10. To evaluate the anti oxidant potential of herbal extracts using DPPH free radical scavenging assay.
11. To evaluate the cytotoxic effect of herbal extracts using MTT assay.
12. To evaluate the nitric oxide (NO) modulatory effect of herbal extracts using Griess method.
13. Biotransformation study
14. Assay of Paracetamol using UV-Visible spectrophotometer

TOTAL: 90 PERIODS

TEXT BOOKS AND 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. By Jaime N. Delgado (Editor), Ole Gisvold (Editor), William A. Remers (Editor). Lippincott Williams & 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. Phytochemistry Vol 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 Rapheal Ikan.

BP9132

IMMUNOTECHNOLOGY LAB

L T P C
0 0 6 3

1. Selection and Handling of animals, Preparation of antigens, Immunization and methods 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. Double diffusion, Immuno-electrophoresis and Radial Immuno diffusion.
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. Hybridoma technology and monoclonal antibody production
16. Demonstration of Immunodiagnosics using commercial kits (Rapid Dot Blot and Strip Test)

TOTAL: 90 PERIODS

TEXT BOOKS AND REFERENCES

1. Kuby, RA Goldsby, Thomas J. Kindt, Barbara, A. Osborne Immunology, 6th Edition, Freeman, 2002.
2. Mary Louise Turgeon, Immunology and Serology in Laboratory Medicine, 2nd Edition, Elsevier, 2007
3. Brostoff J, Seaddin JK, Male D, Roitt IM., Clinical Immunology, 6th Edition, Gower Medical Publishing, 2002.
4. John E. Coligan, John E. Coligan, ADA M. Kruisbeek, Current Protocols in Immunology, 4th Edition John Wiley & Sons, Inc, 1994
5. Paul, Fundamental of Immunology, 4th edition, Lippencott Raven, 1999

BT9153 **APPLIED MATHEMATICS FOR BIOTECHNOLOGISTS** **L T P C**
3 0 0 3

UNIT I PARTIAL DIFFERENTIAL EQUATIONS **9**
First order and second order-application to biology.Lagrange's method and Charpits method.

UNIT II PROBABILITY AND STATISTICS **9**
Probability –Addition theorem, Multiplication theorem and conditional probability-Baye's theorem. Binomial distribution, Poisson distribution and Normal distribution.

UNIT III CURVE FITTING **9**
Curve fitting –fitting a straight line and second degree curve. Correlation and Regression. Fitting a non linear curve. Bivariate correlation application to biological sciences.

UNIT IV SAMPLING DISTRIBUTIONS **9**
Sampling distributions-Large samples and Small samples. Testing of Null hypothesis-Z test, t test and χ^2 test. Type I and Type II errors. Fisher's F Test. Goodness of fit.

UNIT V DESIGN OF EXPERIMENTS **9**
Design of Experiments –One way, Two way classifications – Randomied Block Designs-Latin Square Designs.

TOTAL: 45 PERIODS

TEXT BOOKS

1. Higher Engineering Mathematics 37th Edition. By Grewal.
2. Comprehensive Statistical Methods By P.N.Arora, Sumeet Arora, S.Arora. S.Chand & Co

REFERENCES

1. Probability and Statistics for Engineers 6th Edition. Prentice Hall By R.A.Johnson.
2. Statistical Quality control for the Food Industry. By MERTON R .HUBBARD
3. Mathematical Statistics By V.C.Kapoor and Gupta.

BP9158 **ADVANCED MATHEMATICS** **L T P C**
3 0 0 3

UNIT I CALCULUS REVIEW **9**
Calculus (Quick review of concepts): Review of limits, continuity, differentiability; Mean value theorem, Taylor's Theorem, Maxima and Minima; Fundamental theorem of Calculus; Improper integrals; Applications to area, volume; Convergence of sequences and series; Power series; Partial Derivatives; Gradient and Directional derivatives; Chain rule; Maxima and Minima.

UNIT II ORDINARY DIFFERENTIAL EQUATIONS **9**
First order differential equations: Exact equations, Integrating factors and Bernoulli equations.

UNIT III SECOND AND HIGHER ORDER DIFFERENTIAL EQUATIONS **9**
Linear ODE's with constant coefficients: the characteristic equations; Cauchy-Euler equations; Linear dependence and Wronskians; Method of undetermined coefficients; Method of variation of parameters; Laplace transforms: Inverse theorem, shifting theorems, partial fractions.

UNIT IV LINEAR ALGEBRA 9

Basics: Vectors, matrices, determinants; Matrix addition and multiplication; Systems of equations: Gauss elimination, Matrix rank, Linear independence, Cramer's rule; Inverse of a matrix: Gauss-Jordan elimination; Eigenvalues and Eigenvectors: characteristic polynomials, eigenvalues of special matrices(orthogonal, unitary, hermitian, symmetric, skewsymmetric, normal).

UNIT V NUMERICAL METHODS 9

Solution of equations by iteration; Interpolation by polynomials; Piecewise linear and cubic splines; Numeric integration and differentiation; Linear systems: Gauss elimination, Gauss-Siedel, matrix inversion; LU factorization; Matrix eigenvalues; Numerical solution of ODEs: Euler and Runge-Kutta methods, Predictor-Corrector methods; Exposure to software packages like Matlab or Scilab.

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. G. B. Thomas and R. L. Finney, Calculus and Analytic Geometry, 9th Edition, ISE Reprint, Addison-Wesley, 1998.
2. E. Kreyszig, Advanced engineering mathematics, 8th Edition, John Wiley, 1999.
3. W. E. Boyce and R. DiPrima, Elementary Differential Equations, 8th Edition, John Wiley, 2005.

**BT9113 IPR AND BIOSAFETY L T P C
3 0 0 3**

UNIT I INTRODUCTION TO INTELLECTUAL PROPERTY 9

Types of IP: Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications, Protection of GMOs IP as a factor in R&D; IPs of relevance to Biotechnology and few Case Studies

UNIT II AGREEMENTS AND TREATIES 9

History of GATT & TRIPS Agreement; Madrid Agreement; Hague Agreement; WIPO Treaties; Budapest Treaty; PCT; Indian Patent Act 1970 & recent amendments

UNIT III BASICS OF PATENTS AND CONCEPT OF PRIOR ART 9

Introduction to Patents; Types of patent applications: Ordinary, PCT, Conventional, Divisional and Patent of Addition; Specifications: Provisional and complete; Forms and fees Invention in context of "prior art"; Patent databases; Searching International Databases; Country-wise patent searches (USPTO, esp@cenet(EPO), PATENTScope(WIPO), IPO, etc.)

UNIT IV PATENT FILING PROCEDURES 9

National & PCT filing procedure; Time frame and cost; Status of the patent applications filed; Precautions while patenting – disclosure/non-disclosure; Financial assistance for patenting - introduction to existing schemes Patent licensing and agreement Patent infringement- meaning, scope, litigation, case studies

UNIT V BIOSAFETY 9

Introduction; Historical Background; Introduction to Biological Safety Cabinets; Primary Containment for Biohazards; Biosafety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals; Biosafety guidelines - Government of India; Definition of GMOs & LMOs; Roles of Institutional Biosafety Committee, RCGM, GEAC etc. for GMO applications in food and agriculture; Environmental release of GMOs; Risk Analysis; Risk Assessment; Risk management and communication; Overview of National Regulations and relevant International Agreements including Cartagena Protocol.

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. BAREACT, Indian Patent Act 1970 Acts & Rules, Universal Law Publishing Co. Pvt. Ltd., 2007
2. Kankanala C., Genetic Patent Law & Strategy, 1st Edition, Manupatra Information Solution Pvt. Ltd., 2007

**BP9154 DRUG DOSAGE FORMS AND DESIGN L T P C
3 0 0 3**

UNIT I INTRODUCTION 9

History & Evolution; Definitions; Subject Classifications Oral, Parenteral, Topical, Rectal and Nasal - Physiology of the absorbing membranes; Pharmaco-kinetics; Mechanism of drug absorption; Transport of Drugs; Factors affecting bio-availability- Physiological, Physicochemical Formulation factors.

UNIT II DRUG ACTION AND PREFORMULATION STUDIES 9

Mechanism of Drug action; Receptor theory - Disease , Diagnosis & Treatment; Selection of Drugs; Selection of Dosage Forms; Concept, Therapeutic Justification; Physical properties of drugs; Compatibility, Stability; Solubility, Dissolution, and Bioavailability; Formulation Excipients and Principles; Development of Formulation and Analysis.

UNIT III PHARMACEUTICAL PROCESSING 9

Mixing; Milling; Drying; Compression; Coating; Filling; Sealing; Solubility; Filtration, Clarification, Sieving; Emulsion, Suspension; Sterilization & Disinfectant; Fermentation Process; Synthetic Process

UNIT IV FORMULATION OF DRUGS AND TESTING & STABILITY 9

Tablets; Capsules; Semi solids, Ointments, Cream, Gel, Paste; Suppositories; Powders, Granules; Parenterals; Liquids,(Solutions, Suspensions, Emulsions); Nasal; Ophthalmic and Otic Preparations; Packaging - Bulk Formulation: Liquid orals, parenterals, Oral unit dosage forms

UNIT V PRODUCTION MANAGEMENT 9

Design of the Premises; Machinaries,; Utilities, Services; Operations; Capacity Utilization; Costing, Economics

TOTAL: 45 PERIODS

BT9152 ENZYME TECHNOLOGY AND INDUSTRIAL APPLICATIONS L T P C
3 0 0 3

UNIT I KINETICS AND MECHANISM OF ENZYME ACTION 8

Classification of enzymes; quantification of enzyme activity and specific activity. Estimation of Michaelis Menten parameters, Effect of pH and temperature on enzyme activity, kinetics of inhibition. Modeling of rate equations for single and multiple substrate reactions.

UNIT II IMMOBILISED ENZYME REACTIONS 9

Techniques of enzyme immobilisation-matrix entrapment, ionic and cross linking, column packing; Analysis of mass transfer effects of kinetics of immobilised enzyme reactions; Analysis of Film and Pore Diffusion Effects on Kinetics of immobilized enzyme reactions; calculation of Effectiveness Factors of immobilized enzyme systems; Bioconversion studies with immobilized enzyme packed -bed reactors.

UNIT III MASS TRANSFER EFFECTS IN IMMOBILISED ENZYME SYSTEMS 5

Analysis of film and Pore diffusion Effects on kinetics of immobilised enzyme reactions; Formulation of dimensionless groups and calculation of Effectiveness Factors

UNIT IV APPLICATION OF ENZYMES 12

Extraction of commercially important enzymes from natural sources; Commercial applications of enzymes in food, pharmaceutical and other industries; enzymes for diagnostic applications. Industrial production of enzymes. Use of enzymes in analysis-types of sensing-gadgetry and methods. Case studies on application - chiral conversion, esterification etc.,

UNIT V ENZYME BIOSENSORS 11

Applications of enzymes in analysis; Design of enzyme electrodes and case studies on their application as biosensors in industry, healthcare and environment.

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Blanch, H.W., Clark, D.S. Biochemical Engineering, Marcel Dekker, 1997
2. Lee, James M. Biochemical Engineering, PHI, USA.
3. Bailey J.E. & Ollis, D.F. Biochemical Engineering Fundamentals, 2nd Ed., McGraw Hill, 1986
4. Wiseman, Alan. Hand book of Enzyme Biotechnology, 3rd ed., Ellis Harwood 1995.

BT9169 MOLECULAR THERAPEUTICS L T P C
3 0 0 3

UNIT I 9

Gene therapy; Intracellular barriers to gene delivery; Overview of inherited and acquired diseases for gene therapy; Retro and adeno virus mediated gene transfer; Liposome and nanoparticles mediated gene delivery

UNIT II 9

Cellular therapy; Stem cells: definition, properties and potency of stem cells; Sources: embryonic and adult stem cells; Concept of tissue engineering; Role of scaffolds; Role of growth factors; Role of adult and embryonic stem cells; Clinical applications; Ethical issues

UNIT III **9**
Recombinant therapy; Clinical applications of recombinant technology; Erythropoietin; Insulin analogs and its role in diabetes; Recombinant human growth hormone; Streptokinase and urokinase in thrombosis; Recombinant coagulation factors

UNIT IV **9**
Immunotherapy; Monoclonal antibodies and their role in cancer; Role of recombinant interferons; Immunostimulants; Immunosuppressors in organ transplants; Role of cytokine therapy in cancers; Vaccines: types, recombinant vaccines and clinical applications

UNIT V **9**
Gene silencing technology; Antisense therapy; si RNA; Tissue and organ transplantation; Transgenics and their uses; Cloning; Ethical issues

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Bernhard Palsson and Sangeeta N Bhatia, Tissue Engineering, 2nd Edition, Prentice Hall, 2004.
2. Pamela Greenwell, Michelle McCulley, Molecular Therapeutics: 21st century medicine, 1st Edition, Springer, 2008.

BT9170 **CLINICAL TRIALS AND BIOETHICS** **L T P C**
3 0 0 3

UNIT I **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 21st century; International perspectives; Principles of the International Committee on Harmonisation (ICH)-GCP.

UNIT II **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 **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; the 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 regulation regarding use of animals in research.

UNIT IV **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 **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

TEXT BOOKS

1. Clinical Trial: Study Design, Clinical Trial protocol Placebo controlled study, F.P.Miller, AF Vandome and J Mc Brewster, Alphascript Publications, 2009
2. Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine VI A.Jonson, M.Seegler, w.Winslade, 'Mc Graw Hill, VI Edition, 2006.
3. Bioethics : An Introduction to history method and practice,N.S.Jecker , A.R.Jonsen , R.A.Pearlman, Jones and Bartlett India pvt.ltd , IIInd Edition , 2010.

BP9163 **PHARMACOGENOMICS** **L T P C**
3 0 0 3

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, 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 out come 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 out come 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 of 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

TEXT BOOKS AND REFERENCES

1. Bacterial Pathogenesis- A Molecular Approach - Abigail A.Salyers
2. Principles of Bacterial Pathogenesis – Groisman
3. Structural Biology of Bacterial Pathogenesis – Gabriel Waksman, Michael Caparon
4. Bacterial Pathogenesis – Virginia L.Clark
5. Methods in Microbiology – Bacterial Pathogenesis – Peter Williams
6. Microbial Pathogenesis – Bruce A.McClane
7. Biology of Microorganisms – Michael T.Madigan
8. Genetic analysis of Pathogenic bacteria – Stanley
9. Molecular Infection Biology – Jorg Hacker

BP9165

PHARMACOGNOSY

L T P C
3 0 0 3

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 9

Pyridine and piperidine alkaloids, Tropane alkaloids, Quinoline alkaloids, isoquinoline alkaloids, Indole alkaloids, Imidazole alkaloids, Steroidal alkaloids, Alkaloidal amines purine bases.

UNIT IV PROTEINS VITAMINS AND ANTIBIOTICS 9

Enzyme and other proteins Vitamin and vitamin-containing drug Antibiotics

UNIT V MOLECULES FROM MARINE ORGANISMS 9

Classification of Durg Molecules of marine organisms – Cytotoxic / Anti neoplastic agents cardio vascular – Actie drug – marine toxins – antimicrobial substances – anti – inflammatory and Antispasmodie agents

TOTAL: 45 PERIODS

TEXT BOOKS

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, Nirali Prakashan, 2004.

UNIT II MONITORING OF BIOPROCESSES 6

On-line data analysis for measurement of important physico-chemical and biochemical parameters; Methods of on-line and off-line biomass estimation; microbial calorimetry; Flow injection analysis for measurement of substrates, product and other metabolites; State and parameter estimation techniques for biochemical processes. Case studies on applications of FIA and Microbial calorimetry.

UNIT III MODERN BIOTECHNOLOGICAL PROCESSES 14

Recombinant cell culture processes, guidelines for choosing host-vector systems, plasmid stability in recombinant cell culture, limits to over expression, Modelling of recombinant bacterial cultures; Bioreactor strategies for maximizing product formation; Case studies on high cell density cultivation and plasmid stabilization methods. Bioprocess design considerations for plant and animal cell cultures. Analysis of multiple interacting microbial populations – competition: survival of the fittest, predation and parasitism: Lotka Volterra model.

UNIT IV DESIGN AND ANALYSIS OF BIOLOGICAL REACTORS 11

Ideal bioreactors-batch, fed batch, continuous, cell recycle, plug flow reactor, two stage reactors, enzyme catalyzed reactions. Reactor dynamics and stability. Reactors with non ideal mixing. Other types of reactors- fluidized bed reactors, packed bed reactors, bubble column reactors, trickle bed reactors.

UNIT V SCALEUP OF REACTORS 5

Scaleup by geometry similitude, oxygen transfer, power correlations, mixing time

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Moser, Anton, Bioprocess Technology: Kinetics and Reactors, Springer Verlag, 1988.
2. Bailey J.E. & Ollis, D.F. Biochemical Engineering Fundamentals, 2nd ed., McGraw Hill, 1986
3. Lee, James M. Biochemical Engineering, PHI, USA. Atkinson, Handbook of Bioreactors, 2001
4. Blanch, H.W. Clark, D.S. Biochemical Engineering, Marcel Decker, 1999

**BP9168 COMBINATORIAL METHODS IN BIOPHARMACEUTICS L T P C
3 0 0 3**

UNIT I INTRODUCTION 10

The Original Combinatorial Chemist – Biopolymers constitute natural libraries – Selection and evolution – The expression of genetic information – Combinatorial assembly of antibody genes – Molecular solutions to Combinatorial problems.

UNIT II SYNTHETIC PEPTIDE LIBRARIES 8

Solid-Phase peptide synthesis – Peptide on pins – Other iterative deconvolution strategies, Examples of Split/Couple/Mix Peptide Libraries – Positional Scanning

UNIT III SUPPORTS, LINKERS, AND REAGENTS FOR PEPTIDE AND SMALL MOLECULE SYNTHESIS 10

Polystyrenes – PEG – Grafted supports – Coupling strategies – New resins and linkers – Ring – forming cleavage – loading.

UNIT IV SUPPORTED SOLUTION – PHASE SYNTHESIS 7

Polyethylene glycols – Dendrimers Fluorous synthesis – Solution – Phase parallel synthesis scavenging resins – Ion Exchange resins – Supported reagents – Fluorous reagents – Solid phase extraction – Gas Phase separation.

UNIT V ANALYTICAL METHODS FOR SOLID-PHASE SYNTHESIS 10

Product identification – Gel Phase NMR – High resolution magic angle spinning NMR on-bead infrared Spectroscopy – Mass Spectroscopy – Non Spectroscopic Methods

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Fenniri, Hicham, 'Combinatorial Chemistry', Oxford University Press, 2000
2. Block J.H. and Beale, J.M., 'Wilson & Gisvolds Text book of Organic Medicinal and Pharmaceutical Chemistry', 11th Edition, Lippincott Williams & Wilkins, 2004
3. Fassina, G. "Combinatorial Chemistry and Technologies: Methods and Applications", 2nd Edition, CRC Press, 2005.

**BP9169 NANOBIO TECHNOLOGY L T P C
3 0 0 3**

UNIT I NANOSCALES 5

What is meant by Nanoscale – Nanoscale Processes – Physical and Chemical Properties of Materials in the Nanoscales - Nanoscale Measurements .

UNIT II PROPERTIES AND MEASUREMENTS OF NANOMATERIAL 8

Optical Properties – Absorption and Fluorescence – Microscopy measurements – SEM – TEM - AFM and STM. Confocal and TIRF. Imaging

UNIT III NANOBIOLOGY 8

Properties of DNA and motor proteins – Measurements of Conductivity of DNA nanowires and angular properties of motor -- Lessons from Nature on making nanodevices.

UNIT IV BIOCONJUGATION OF NANOMATERIALS TO BIOLOGICAL MOLECULES 6

Reactive Groups on biomolecules (DNA & Proteins) - Conjugation to nanoparticles (ZnS- Fe₃O₄) - Uses of Bioconjugated Nanoparticles

UNIT V NANO DRUG DELIVERY 3

Various Drug Delivery Systems – aerosol - Inhalants - Injectibles – Properties of Nanocarriers – Efficiency of the Systems.

Practicals:**15**

1. Preparation of Silver Nanoparticles by Chemical Methods
2. Characterization of ZnS nanoparticles by Optical Methods.
3. Templated Synthesis of Fe₃O₄ Nanoparticles
4. AFM of ZnS nanoparticles.
5. SEM & HRTEM Analysis of silver and Fe₃O₄ Nanoparticles
6. Bacterial Synthesis of ZnS Nanoparticles.
7. Confocal & TIRF Microscopy of ZnS particles Interaction with Cell lines

TOTAL: 45 PERIODS**TEXT BOOKS AND REFERENCES**

1. Nanobiotechnology: Concepts, Applications and Perspectives , Christof M. Niemeyer (Editor), Chad A. Mirkin (Editor) , Wiley-VCH; 1 edition , 2004.
2. NanoBioTechnology: BioInspired Devices and Materials of the Future by Oded Shoseyov and Ilan Levy, Humana Press; 1 edition 2007.
3. NanoBiotechnology Protocols (Methods in Molecular Biology) by Sandra J Rosenthal and David W. Wright , Humana Press; 1 edition , 2005.

BP9170**IMMUNOTECHNOLOGY****L T P C****3 0 0 3****UNIT I IMMUNE SYSTEM****4**

Introduction; cells of the immune system and their development; primary and secondary lymphoid organs.

UNIT II IMMUNOGLOBULINS**12**

Antigens, adjuvants, antibodies – Polyclonal; Hybridoma technology for monoclonal antibody production; application of monoclonal antibodies and idiotypic antibodies; catalytic antibodies; humanized monoclonal antibodies; Enzyme linked immunosorbant assay (ELISA); Radio immunoassay (RIA).

UNIT III ANTIGEN PROCESSING AND PRESENTATION**5**

Major Histocompatibility complex; antigen presenting cells and their characteristics.

UNIT IV CELLULAR IMMUNOLOGY**14**

Characterization and functions of T cell subsets; Hypersensitivity reactions; lymphoproliferative assay; mixed lymphocyte reaction (MLR); graft vs host reaction; cell mediated lympholysis (CML); cytotoxicity assays; macrophages and their functions; in situ characterization of cells.

UNIT V IMMUNOTHERAPY**10**

Cytokines and their characteristics, functions and assays, vaccine technology, DNA based vaccines; pathogenesis of infections by microorganisms. Antibody Engineering and its application – catalytic antibodies and humanized monoclonal antibodies.

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Riott I.M., Brostoff J. and Male D., "Immunology", 6th Edition, Mosby Pub., 1993
2. Reeves G. and Todd I. "Lecture Notes in Immunology", Blackwell Scientific Publishers, London, UK, 1996
3. Weir D.M., 'Immunology' 8th Edition, Churchill Livingston.
4. Goldsby R.A., 'Immunology', W.H.Freeman & Company, N.Y. 2005

BP9171 RESEARCH AND RESEARCH METHODOLOGY L T P C **IN BIOTECHNOLOGY 3 0 0 3**

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 (bench to 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 of biotech research, sources of literature for biotech research

UNIT III EXPERIMENTAL RESEARCH: BASIC CONCEPTS IN DESIGN AND METHODOLOGY 9

Precision, accuracy, sensitivity and specificity; variables, biochemical measurements, types of measurements, enzymes and enzymatic analysis, antibodies and immunoassays, 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 of analysis (analytical, objective, subjective) and cross verification, correlation with published results, 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 their specifications, Ways to protect intellectual property – Patents, technical writing skills, definition and importance of impact factor and citation index - assignment in technical writing

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

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