ANNA UNIVERSITY:: CHENNAI 600 025
AFFILIATED INSTITUTIONS
M. TECH. BIOPHARMACEUTICAL TECHNOLOGY
REGULATIONS – 2017
CHOICE BASED CREDIT SYSTEM

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. Graduates 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. Graduates will demonstrate skills to employ modern technology, software and equipment to analyze problems.
7. Graduates will demonstrate knowledge of professional and ethical responsibilities.
8. Graduates will be able to exhibit scientific communication effectively in both verbal and written form.
9. Graduates will show the understanding of impact of pharmaceutical technology on the society and also will be aware of contemporary issues.
10. Graduates will develop confidence for self education and ability for life-long learning.

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

	SUBJECTS	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
	SEMESTER - I										
	Biostatistics	✓	✓	✓							
	Drug Dosage Forms and Design			✓	✓	✓					
	Biogenerics and Biopharmaceuticals		✓	✓	✓	✓					
	Gene Manipulation Technology			✓	✓	✓	✓				
	Formulation and Analytical Techniques in Biopharmaceutical Technology Laboratory			✓	✓	✓	✓				
	Professional Elective – I										
	Genomics and Proteomics	✓	✓	✓			✓			✓	
	Human Physiology and Drug Metabolism	✓	✓							✓	✓
	Bioconjugate Technology and Applications	✓		✓	✓			✓		✓	
	Chemistry of Natural Products		✓		✓		✓		✓		
	Professional Elective – II										
	Molecular Medicine and Mechanism		✓	✓		✓		✓	✓		
	Clinical Trials and Bioethics	✓	✓		✓		✓		✓		✓
	Biocatalysts and Enzyme Technology	✓		✓	✓					✓	✓
	Protein Engineering and Industrial	✓	✓	✓	✓	✓				✓	✓

	Applications										
	Professional Elective - III										
	Microbial Technology	✓	✓	✓		✓		✓		✓	✓
	Pharmacology										
	Advanced Technologies in Omics Sciences	✓	✓	✓			✓			✓	
	Metabolic Process and Engineering	✓		✓		✓		✓	✓		
	SEMESTER - II										
	Pharmacokinetics and Pharmacodynamics	✓	✓		✓		✓		✓		
	Drug Regulatory, Quality and Safety Evaluation		✓	✓		✓		✓			✓
	Immunopharmacology	✓		✓		✓	✓		✓		
	Fermentation Technology	✓		✓	✓		✓			✓	
	Immunopharmacology Laboratory	✓		✓	✓	✓	✓	✓	✓	✓	✓
	Professional Elective – IV										
	Pharmacogenomics	✓		✓		✓	✓		✓		✓
	Conventional and Rationale Drug Discovery Strategies	✓	✓		✓		✓		✓		✓
	Nanobiotechnology		✓		✓	✓		✓	✓		✓
	Research and Research Methodology in Biotechnology	✓		✓	✓		✓	✓			✓
	Professional Elective – V										
	Advanced Analytical Techniques for Biologist	✓		✓	✓		✓		✓		✓
	Herbal Drug Development and Standardization	✓	✓		✓	✓		✓			✓
	Advanced Cancer Biology		✓	✓		✓		✓	✓		
	Entrepreneurship and Intellectual Property Rights	✓	✓		✓		✓		✓		✓
	Professional Elective – VI										

	Tissue Engineering and Regenerative Medicine	✓		✓	✓		✓		✓		✓
	Novel Drug Delivery System		✓	✓		✓		✓			✓
	Bioseperation Technology	✓		✓	✓			✓		✓	
	Biomaterials	✓	✓		✓		✓				✓
	SEMESTER - III										
	Project work (Phase – I)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Drug discovery Laboratory	✓		✓	✓		✓		✓		
	Pre-clinical Laboratory	✓	✓		✓		✓	✓			✓
	SEMESTER - IV										
	Project Work (Phase – II)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

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I TO IV SEMESTERS CURRICULUM AND SYLLABUS

SEMESTER I

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
THEORY								
1	BO5101	Biostatistics	FC	4	4	0	0	4
2	BO5102	Drug Dosage forms and Design	PC	3	3	0	0	3
3	BO5103	Biogenerics and Biopharmaceuticals	PC	3	3	0	0	3
4	BO5104	Gene Manipulation Technology	PC	3	3	0	0	3
5		Professional Elective I	PE	3	3	0	0	3
6		Professional Elective II	PE	3	3	0	0	3
7		Professional Elective III	PE	3	3	0	0	3
PRACTICAL								
8	BO5111	Formulation and Analytical Techniques in Biopharmaceutical Technology Laboratory	PC	6	0	0	6	3
			TOTAL	**28**	**22**	**0**	**6**	**25**

SEMESTER II

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
THEORY								
1	BO5201	Pharmacokinetics and Pharmacodynamics	PC	3	3	0	0	3
2	BO5202	Drug Regulatory, Quality and Safety Evaluation	PC	3	3	0	0	3
3	BO5203	Immunopharmacology	PC	3	3	0	0	3
4	BO5204	Fermentation Technology	PC	3	3	0	0	3
5		Professional Elective IV	PE	3	3	0	0	3
6		Professional Elective V	PE	3	3	0	0	3
7		Professional Elective VI	PE	3	3	0	0	3
PRACTICALS								
8	BO5211	Immunopharmacology Laboratory	PC	6	0	0	6	3
			TOTAL	**27**	**21**	**0**	**6**	**24**

SEMESTER III

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
THEORY								
1	BO5311	Drug Discovery Laboratory	**PC**	6	0	0	6	3
2	BO5312	Pre-clinical Laboratory	**PC**	6	0	0	6	3
PRACTICAL								
3	BO5313	Project work (Phase – I)	**EEC**	12	0	0	12	6
			TOTAL	**24**	**0**	**0**	**24**	**12**

SEMESTER IV

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
PRACTICAL								
1	BO5411	Project Work (Phase – II)	**EEC**	24	0	0	24	12
			TOTAL	**24**	**0**	**0**	**24**	**12**

TOTAL CREDITS:73

SEMESTER I, PROFESSIONAL ELECTIVES I

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
1	BO5001	Genomics and Proteomics	PE	3	3	0	0	3
2	BO5002	Human Physiology and Drug Metabolism	PE	3	3	0	0	3
3	BO5003	Bioconjugate Technology and Applications	PE	3	3	0	0	3
4	BO5004	Chemistry of Natural Products	PE	3	3	0	0	3

SEMESTER I, PROFESSIONAL ELECTIVES II

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
1	BO5005	Molecular Medicine and Mechanism	PE	3	3	0	0	3
2	BO5006	Clinical Trials and Bioethics	PE	3	3	0	0	3
3	BO5007	Biocatalysts and Enzyme Technology	PE	3	3	0	0	3
4	BO5008	Protein Engineering and Industrial Applications	PE	3	3	0	0	3

SEMESTER I, PROFESSIONAL ELECTIVES III

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
1	BO5009	Microbial Technology	PE	3	3	0	0	3
2	BO5010	Pharmacology	PE	3	3	0	0	3
3	BO5011	Advanced Technologies in Omics Sciences	PE	3	3	0	0	3
4	BO5012	Metabolic Engineering	PE	3	3	0	0	3

SEMESTER II, PROFESSIONAL ELECTIVES IV

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
1	BO5013	Pharmacogenomics	PE	3	3	0	0	3
2	BO5014	Conventional and Rationale Drug Discovery Strategies	PE	3	3	0	0	3
3	BO5015	Nanobiotechnology	PE	3	3	0	0	3
4	BO5016	Research and Research Methodology in Biotechnology	PE	3	3	0	0	3

SEMESTER II, PROFESSIONAL ELECTIVES V

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
1	BO5017	Advanced Analytical Techniques for Biologist	PE	3	3	0	0	3
2	BO5018	Herbal Drug Development and Standardization	PE	3	3	0	0	3
3	BO5019	Advanced Cancer Biology	PE	3	3	0	0	3
4	BO5020	Entrepreneurship and Intellectual Property Rights	PE	3	3	0	0	3

SEMESTER II, PROFESSIONAL ELECTIVES VI

Sl. No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
1	BO5091	Tissue Engineering and Regenerative Medicine	PE	3	3	0	0	3
2	BO5021	Novel Drug Delivery System	PE	3	3	0	0	3
3	BO5022	Downstream Processing	PE	3	3	0	0	3
4	BO5092	Biomaterials	PE	3	3	0	0	3

Foundation Courses (FC)

S.No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
THEORY								
1.	BO5101	Biostatistics	FC	4	4	0	0	4

Professional Core (PC)

S.No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
THEORY								
1.	BO5102	Drug Dosage forms and Design	PC	3	3	0	0	3
2.	BO5103	Biogenerics and Biopharmaceuticals	PC	3	3	0	0	3
3.	BO5104	Gene Manipulation Technology	PC	3	3	0	0	3
4.	BO5111	Formulation and Analytical Techniques in Biopharmaceutical Technology Laboratory	PC	6	0	0	6	3
5.	BO5201	Pharmacokinetics and Pharmacodynamics	PC	3	3	0	0	3
6.	BO5202	Drug Regulatory, Quality and Safety Evaluation	PC	3	3	0	0	3
7.	BO5203	Immunopharmacology	PC	3	3	0	0	3
8.	BO5204	Fermentation Technology	PC	3	3	0	0	3
9.	BO5211	Immunopharmacology Laboratory	PC	6	0	0	6	3
10.	BO5311	Drug Discovery Laboratory	**PC**	6	0	0	6	3
11.	BO5312	Pre-clinical Laboratory	**PC**	6	0	0	6	3

Employability Enhancement Courses (EEC)

S.No	COURSE CODE	COURSE TITLE	CATE GORY	CONTACT PERIODS	L	T	P	C
THEORY								
1.	BO5313	Project work (Phase I)	**EEC**	12	0	0	12	6
2.	BO5411	Project Work (Phase II)	**EEC**	24	0	0	24	12

BO5101 **BIOSTATISTICS** **L T P C**
(For Biopharmaceutical Technology) **4 0 0 4**

OBJECTIVES :

- This course is designed to provide a solid foundation on topics in statistics that can be useful for the biotechnologists to conduct research on different types of data arising in public health and clinical studies. It is framed to address the issues in biotechnology using the concepts on probability, correlation, regression, sampling, estimation theory, testing of hypothesis and design an analysis of experiments.

UNIT I RANDOM VARAIBLE AND PROBABILITY DISTRIBUTION 12

Discrete random variable – Probability mass function – Continuous random variable – Probability density function – Moments : Mean and variance with properties – Special distributions : Binomial, Poisson, Geometric, Uniform, Exponential, Gamma, Weibull and Normal – Properties - Simple problems.

UNIT II CORRELATION AND REGRESSION 12

Correlation coefficient – Properties – Problems – Rank correlation – Multiple and partial correlation – Plane of regression – Properties of residuals – Coefficient of multiple correlation – Coefficient of partial correlation – Multiple correlation with total and partial correlations – Regression and partial correlations in terms of lower order coefficients.

UNIT III SAMPLING DISTRIBUTION AND ESTIMATION THEORY 12

Random sampling – Sample mean and variance – Standard error – Estimator: Unbiasedness – Maximum likelihood estimation – Method of moments – Curve fitting by the method of least squares – Fitting curves of the form $y = ax + b$, $y = ax^2 + bx + c$, $y = ab^x$ and $y = ax^b$ - Multiple regression lines.

UNIT IV TESTING OF HYPOTHESIS 12

Sampling distributions – Type I and Type II errors – Tests based on Normal, t, χ^2 and F distributions for testing of mean, difference between two means, proportions, difference between two proportions, variance, ratio of two variances – Independence of attributes (r x c contingency table) - Goodness of fit.

UNIT V DESIGN OF EXPERIMENTS 12

Completely random design –Randomized complete block design– Analysis of variance : One - way and two - way classifications – Latin square design - 2^2 factorial design.

TOTAL : 60 PERIODS

OUTCOMES :

After completing this course, students should demonstrate competency in the following topics:

- Basic probability axioms and rules and the moments of discrete and continuous random variables.

- Distributions and their properties
- Least squares, correlation, regression, consistency, efficiency and unbiasedness of estimators, method of maximum likelihood estimation and Central Limit Theorem.
- Sampling and use statistical tests in testing hypotheses on data.
- List the guidelines for designing experiments, recognize the key historical figures in Design of Experiments, conduct statistical tests and analyze the results.

The students should have the ability to use the appropriate and relevant, fundamental and applied mathematical and statistical knowledge, methodologies and modern computational tools.

REFERENCES :

1. Devore, J.L., "Probability and Statistics for Engineering and Sciences", 8th Edition, Cengage Learning Pvt. Ltd., New Delhi, 2014.
2. Freund, J.E., "Mathematical Statistics", 5th Edition, Prentice Hall of India, 2001.
3. Gupta, S.C. and Kapoor, V. K, "Fundamental of Mathematical Statistics", Sultan Chand and Sons, 14th Edition, 2016.
4. Johnson, R.A and Gupta. C. B., "Miller and Freund's Probability and Statistics for Engineers", Pearson Education, Asia, 8th Edition, 2011.
5. Wayane, W. Daniel, "Biostatistics: A Foundation for Analysis in the Health Sciences", 5th Edition, John wiley & Sons Inc., 1991, New York.

BO5102 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 and understanding the theoretical principles with application oriented problems.

UNIT I INTRODUCTION TO DOSAGE FORMS AND PREFORMULATION 9

Definitions and Classification of Dosage forms, Pharmacokinetics/Pharmacodynamics parameters for Dosage form development. Physical properties of drugs - physical form, polymorphism, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic property and their effect on formulation, stability and bioavailability. Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemization, polymerization, etc. and their influence on formulation and stability of products. Stabilization and stability testing protocol for various pharmaceutical products.

UNIT II SOLID DOSAGE FORMS 11

Tablets: Classification, tablet excipients, granulation technology, tablet compression and machinery, processing problems and evaluation. Coating- Types, materials for coating, formulation, equipment's, film defects and evaluation of coated tablets. Capsules: Materials for production of hard/Soft gelatin capsules, size of capsules and method of capsule filling.

Importance of base absorption, manufacturing, quality control, stability and storage of capsule dosage forms.

UNIT III LIQUID AND PARENTRAL DOSAGE FORMS 11

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 in pharmacopoeia. Parenterals; Liquids, (Solutions, Suspensions, Emulsions); Formulation of Parenteral liquids, Evaluation of Parenteral liquids. Nasal; Ophthalmic and Otic Preparations and its Evaluation.

UNIT IV SEMI SOLID AND AEROSOL DOSAGE FORM 5

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 PACKAGING TECHNIQUES 9

Packaging biopharmaceutical dosage design & delivery: Primary and secondary packaging materials. Desirable features and a detailed study of different types of pharmaceutical containers and closures (glass, plastics and rubber), including their merits and demerits; selection and evaluation of pharmaceutical packaging materials

TOTAL: 45 PERIODS

OUTCOME:

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

REFERENCES:

1. Ansel, H.C. “Pharmaceutical Dosage Forms and Drug Delivery Systems”, 10thEdition, Lippincott Williams &Wilkins, 2014.
2. Aulton M.E "Pharmaceutics- The Design and Manufacture of Medicine", 4th Edition, Churchill Livingstone, Elsevier, 2013
3. Kenneth, E.A., Lachmann, L., Liebermann, H.A., Pharmaceutical Dosage Forms: Tablets Vol. 1-3, Marcel Decker, New York, 4th Edition, 1993.
4. Lachmann, L., Libermann, H.A., Kanig, J.L, Theory and Practice of Industrial Pharmacy, Lea &Febiger, London, 3rd Edition, 1999.
5. Lieberman, H.A. “Pharmaceutical Dosage Forms: Tablets”. Vol.1-3, 2ndEdition, MarcelDekker, 2005.
6. Lippincott, “Remington’s The Science and Practice of Pharmacy”, Vo.1 & 2, 20thEdition, William’s Wilkins, 2004.

BO5103 BIOGENERICS AND BIOPHARMACEUTICALS L T P C
3 0 0 3

OBJECTIVES

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

UNIT I BIOGENERICS INTRODUCTION 9

Definition: Generics and its advantages; Biogenetics 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; International Non-proprietary Names (INN) nomenclature system biosimilars regulation (EU position, US pathways, Government initiatives)

UNIT II BIOSIMILARS AND ITS SCENARIO 9

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

UNIT III CHARACTERIZATION OF BIOSIMILARS 9

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

UNIT IV IMMUNOGENECITY OF BIOPHARMACEUTICALS 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 STABILITY ANALYSIS AND CASE STUDIES OF BIOLOGICS 9

Regulatory Stability Guidelines on Biologicals; Stability Designs; Statistical Analysis; Case studies: Erythropoietin, Insulin, Somatotropin, Interleukin-2, Interferon Granulocyte macrophage-CSF, Factor VIIa, Factor IX, Factor VIII, Activated protein C, Tissue plasminogen activator, Monoclonal antibodies etc.

TOTAL : 45 PERIODS

OUTCOME

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

REFERENCES

1. Niazi, Sarfaraz K. “Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues”. CRC, 2002
2. Prugnaud, Jean-Louis, Trouvin, Jean Hugues. “Biosimilars” Springer, 2012
3. Shein-Chung Chow. “Biosimilars: Design and Analysis of Follow-on Biologics” CRC Press, 2013.

BO5104 GENE MANIPULATION TECHNOLOGY L T P C
3 0 0 3

OBJECTIVE

- This subject will give conceptual knowledge in the Cloning & Expression of genes; Construction of DNA libraries & Sequencing; PCR & mutagenesis; Gene transfer & Gene therapy to students.

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, Plasmids, PAC, BAC and YAC. Expression vector – Characteristics, RNA probe synthesis, High level expression of proteins, 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. Differences between gDNA and cDNA library. Screening strategies – Hybridization, PCR, Immunoscreening,South-western and North-Western. Functional cloning – Functional complementation and gain of function. Difference cloning: Differential screening, Subtracted DNA 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 up approach.

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 protein engineering by PCR, RACE, Kuntel's 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 – ImportanceTi Plasmid, Cointegrate and Binary vectors. Overview of Gene therapy

TOTAL : 45 PERIODS

OUTCOME

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

REFERENCES

1. Desmond Nicholl, "An Introduction to Genetic Engineering", Cambridge University Press 2002.
2. Lemonie, N. R. and Cooper, D.N. Gene Therapy, BIOS, 1996.
3. Primrose S.B., Twyman R.H., and Old R.W. "Principles of Gene Manipulation". 6th Edition., Blackwell Science, 2001
4. Winnacker E.L. "From Genes to Clones: Introduction to Gene Technology". Panima,2003

BO5111 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 the analytical methods available for evaluation of pharmaceuticals.

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, odour etc)
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, physiological buffers and determination of buffer capacity.

EQUIPMENTS REQUIRED

1. Granulator
2. Punching machine
3. Capsule filler
4. Disintegration, dissolution and friability testing apparatus
5. pH meter, physical balances

TOTAL: 90 PERIODS

OUTCOME

- Hands on experience to make the students competent in drug formulation to take up challenging industry career.

REFERENCE

1. Ansel, H.C. “Pharmaceutical Dosage Forms and Drug Delivery Systems”, 7th Edition, Lippincott Williams & Wilkins, 2000.
2. Avis, K.E. etal., “Pharmaceutical Dosage Forms: Parenteral Medications”, (Vol.I, II&III) 2nd Rev. Edition, Marcel Dekker, 1992
3. Lachman, Leon etal., “The Theory And Practice of Industrial Pharmacy”, 4th Edition, Varghese Publishing House, 2013.
4. Lieberman, H.A. etal., “Pharmaceutical Dosage Forms: Disperse Systems” (Vol.I,II& III) 2nd Rev. Edition, Marcel Dekker, 1996.
5. Lieberman, H.A. etal., “Pharmaceutical Dosage Forms: Tablets” (Vol. I, II & III) 2th Edition, Marcel Dekker, 1989.

BO5201 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.

UNIT I FUNDAMENTALS ON DRUG ABSORPTION AND DISTRIBUTION 9

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

UNIT II FUNDAMENTALS ON DRUG METABOLISM AND EXCRETION 9

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

UNIT III PHARMACOKINETIC INVESTIGATION AND EVALUATION 9

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

UNIT IV PHARMACODYNAMIC FUNDAMENTALS 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 PK/PD PRINCIPLES IN DOSAGE FORM DEVELOPMENT8

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

TOTAL : 45 PERIODS

OUTCOME

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

REFERENCES

1. Brahmankar, D.M., “Biopharmaceutical and Pharmacokinetics: A Treatise”, VallabhPrakashan, 1995.
2. Notari, R.E., “Biopharmaceutics And Clinical Pharmacokinetics: An Introduction”, 4thedition, MarcellDeckker, 2005
3. Oliver Kayser, Rainer H. Müller, “Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications”, Wiley-VCH Publication,Jan 2004
4. Schoenwald, R.D., “Pharmacokinetics In Drug Discovery And Development”, CRC Press, 2002.

BO5202 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 at International level.

UNIT I INTRODUCTION TO DRUGS & COSMETICS ACT 8

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

UNIT II PHARMACOPOEIA 6

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

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

cGMP concepts – Development, Manufacturing Record, Analytical &Process Validation, Equipment& utility Qualification and Calibration, Personnel procedures; Regulatorybodies & 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 oftrials, bioethics&stakeholders, Bioavailability & Bio equivalence studies.

UNIT V SAFETY AND ENVIRONMENTAL CONTROL 15

Patent act- Patent, Trade Mark Registration, I.P.R; Safety & Environmental control; Project (Regulatory factors).

TOTAL : 45 PERIODS

OUTCOME

- After completion of the course, students would have learnt the principles of drug regulatory affairs and latest information on drug research, manufacturing, sales and distribution.

REFERENCES

1. Abraham, John and Smith, H.W. “Regulation of the Pharmaceutical Industry”, Palgrave, Macmillan, 2003.
2. Berry, Ira R. and Harpaz, Daniel “Validation of Active Pharmaceutical Ingredients”, 2ndEdition, CRC Press, 2001
3. British Pharmacopeia, 2016.
4. Gad, Shayne C. “Drug Safety Evaluation”, Wiley-Interscience, 2002
5. Indian Pharmacopeia, 2014.
6. Malik, Vijay “Drugs and Cosmetics Act, 1940”. EBC Publishing Co, 1998.
7. "Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials”, Vol.I&II, World Health Organization and Pharma Syndicate, 2002.

8. United States Pharmacopeia, 2016.
9. Weinberg, Sandy “Good Laboratory Practice Regulations” 3rd Edition, Marcel Dekker,2003.

BO5203 IMMUNOPHARMACOLOGY L T P C
3 0 0 3

OBJECTIVES

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

UNIT I INTRODUCTION TO PHARMACOLOGY AND IMMUNOLOGY 9

Principles of basic and clinical pharmacokinetics and pharmacodynamics. Adverse drug reactions. Drug interactions, Innate and adaptive immunity, Immunogenicity; Antigenicity; Physiology of immune response, Immunity to virus, bacteria, fungi, Immune cell and organ classification, Relationships between immune and neurohumoral regulations, influence of stress, nutrition and environment on immunity.

UNIT II INTRODUCTION TO VACCINOLOGY 9

Classification, active immunization, vaccines technology, perspective vaccines, means of passive 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 immunodiagnostics, ELISA, Flow cytometry, ELISPOT, immnunoradiology, Basic immunotoxicology - principles of testing of immunomodulating and immunotoxicological properties of drugs and xenobiotics.

UNIT IV TRANSPLANTATION THERAPEUTICS 9

Laws of transplantation, host vs Graft and Graft vs Host reactions; HLA Classification immunosuppressants, drugs for immunosuppressive therapy: corticosteroids, Antimetabolites and calcineurine inhibitors, Clinical aspects of antiallergic, immunosuppressive, immune stimulating and substitutive therapy.

UNIT V IMMUNOLOGY OF ALLERGY 9

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

TOTAL: 45 PERIODS

OUTCOME

On completion of the course, students will be able to

- Understand advanced knowledge in pharmacology of drugs acting on the immune system, their classification, therapeutic use and mechanism of treatment.
- Understand various disease states, life style diseases and identification of novel therapeutic targets related to the diseases.
- Correlate the relationship between immune therapeutics with other drugs and their role in modulation of body's own natural defenses.

REFERENCES

1. David Male Jonathan Brostoff David Roth Ivan Roitt. "Immunology", 8th Edition, Elsevier. 2012
2. Goodman And Gilman's, "The Pharmacological Basis of Therapeutics".12th Edition, 2010.
3. Janeway, C.A., Travers, P., Walport, M. & Shlomchk, M.J. "Immunobiology", 6th Edition, Churchill, Livingstone, 2005.
4. Katzung, B.G., "Basic and Clinical Pharmacology", Prentice Hall International, 12th Edition, 2011.
5. Mycek M.J., Gerlnet S.B And Perper M.M. "Lippincott's Illustrated Pharmacology Reviews", Lipincott Company, Philadelphia.
6. Thomas J. Kindt, Richard A. Goldsby, Barbara A. Osborne. "Kuby Immunology". 6th Edition, W.H. Freeman, 2006.

BO5204 FERMENTATION TECHNOLOGY L T P C
3 0 0 3

OBJECTIVE

- The subject provides knowledge involving basic principle of fermentation process, microbial kinetics and recombinant protein production along with case studies, to help the students understand fermentation processes involved in Pharmaceutical 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, design of sparger, mixing time estimation, oxygen mass transfer capability in bioreactor, Removal of Heat in bioreactor, Main parameters to be monitored and controlled in fermentation processes.

UNIT II MICROBIAL KINETICS AND DESIGN OF VARIOUS CULTIVATION PROCESSES 9

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

UNIT III MODELING OF RECOMBINANT CULTIVATIONANIMAL AND PLANT CELL CULTIVATION SYSTEMSFORTHERAPEUTIC PROTEINS 9

Structured models of metabolism and growth, models of gene expression and regulation, a generalized model of plasmid replication, Genetic instability, predicting host-vector interactions and genetically instability. Process considerations for utilizing genetically engineered strains. Media, aeration in cell culture systems, Bioreactors for plant/animal suspension culture, cell immobilization and organized tissue, bioreactor considerations for animal /plant cell culture for production of pharmaceuticals, Therapeutic proteins and Monoclonal antibodies.

UNIT IV DOWNSTREAM PROCESSING AND SEPARATION TECHNIQUES 9

Characteristics of biological materials: pretreatment methods; Separation of cell mass: centrifugation, clarification and filtration ; Different methods of cell disruption; Advantages; Disadvantages; Solid shear method and liquid shear method; Different concentration methods: evaporation, distillation, crystallization, evaporation, SCFE, solvent extraction, phase separation, drying etc., whole broth extraction, protein precipitation; extraction; adsorption; Modern techniques: Electrophoresis; Chromatographic methods; Ultrafiltration; Reverse osmosis; Cross flow filtration; Microfiltration; Isoelectric focusing; Affinity based separations

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

OUTCOME

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

REFERENCES

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

BO5211 IMMUNOPHARMACOLOGY LABORATORY L T P C
0 0 6 3

OBJECTIVES

- The student will undergo hands on experience on animal handing and various aspects of advanced immunological techniques like Competitive ELISA, Immunoprecipitations, flow cytometry assays and in vitro immunoassays training.

EXPERIMENTS

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. 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 splenocytes and demonstration of T cell proliferation
12. Lymphoproliferation by mitogen/antigen and Thymidine uptake assay
13. Demonstration of cell viability by MTT assay
14. Flow cytometry, 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 Strip Test)

TOTAL: 90 PERIODS

Required Equipments:

Microscopes, restainer (mouse, rat, rabbit), purification columns, microplate reader, UV spectrometer, PAGE apparatus, Western blot apparatus (dry/semi-dry/wet), Flow cytometer, centrifuge, Haemocytometer, required kits, strains & consumables

OUTCOME

The student will be able to

- Acquire various practical skills in modern immunological techniques
- Understand diagnostic tools for various diseases using immunological techniques.
- Impart their acquired knowledge in academic and industrial research.

REFERENCES

1. Brostoff J et al., “Clinical Immunology”, 6th Edition, Gower Medical Publishing, 2002.
2. Coligan, J. E. Et al, “Current Protocols in Immunology”, 4thedition John Wiley & Sons,1991
3. Paul, “Fundamental of Immunology”, 4th Edition, Lippincott Raven, 1999
4. Thomas J. Kindt, Richard A. Goldsby, Barbara A. Osborne. “Kuby Immunology”. 6th Edition, W.H. Freeman, 2006.

5. Turgeon, Mary Louise. “Immunology and Serology in Laboratory Medicine”, 2nd Edition,Elsevier, 2007.

BO5311 DRUG DISCOVERY LABORATORY L T P C
0 0 6 3

OBJECTIVES

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

SYNTHETIC METHODS FOR DRUG DISCOVERY

1. Synthesis of selected drugs involving two or more steps of synthesis and study of spectral analysis of drug synthesized (Paracetamol, Aspirin, Fluorscein, acetanilide, etc.).
2. Determination of pharmacopoeia standards for the synthesized drugs.
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 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 (caffeine acid from tea leaves).
7. To evaluate the antioxidant potential of herbal extracts using DPPH freeRadicalscavenging 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 usingGriessmethod.
10. Biotransformation study

TOTAL : 90 PERIODS

Required Equipments:

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

OUTCOME

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

REFERENCES

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

BO5312 PRE-CLINICAL LABORATORY L T P C

0 0 6 3

OBJECTIVES

- The student will go hands on training and get exposure on preclinical studies and its applications.

EXPERIMENTS

1. Experiments on *in-vitro – in-vivo* correlation studies.
2. Experiments on permeation studies.
3. Experiments *in-vitro* toxicological studies.
4. Experiments on *in-vitro* genotoxicity studies using PCR.
5. Experiments on PK/PD studies.

TOTAL : 90 PERIODS

For a batch of 10 students the following are needed:

1. Dissolution testing apparatus - 2 (PK/PD studies)
2. Disintegration testing apparatus - 2 (PK/PD studies)
3. CO2 incubator for in-vitro growing of cultures for toxicity studies
4. Inverted microscope for cytotoxicity studies
5. Biosafety hoods for handling cultures
6. spectrophotometer for assays
7. PCR machine - 2
8. Ussing Chamber for permeation studies -2
9. Consumables - cell culture plates, micro-titre plates, membranes, reagents

OUTCOME

- Upon successful completion of this course the student able to conduct preclinical studies on given products.

REFERENCES

- H. G. Vogel. "Drug Discovery and Evaluation Pharmacological Assay", Springer 2nd Edition, 2002.

- Handbook of Stability Testing In Pharmaceutical Development, Huynh-Ba, Kim, Springer, 2009
- In Vitro Toxicology, Shayne Cox Gad 2nd Edition, 2000. Taylor & Francis, New York.
- Pharmacokinetics in Drug Discovery and Development by Ronald D. Schoenwald. CRC Press Washington, D.C. 2002

BO5313 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 the students to undertake research in this area.

OUTCOME

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

BO5411 PROJECT WORK – PHASE II LT P C
0 0 24 12

OBJECTIVES

- To provide research training in specific areas of Biopharmaceutical Technology and to developtheir skills for academic and industrial research.

OUTCOME

- The students will be trained to undertake cutting edge research in the area of Biopharmaceutical Technology.

BO5001 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 genomics analyses, and advanced methods and approaches in proteomics.

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.

OUTCOME

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

TOTAL: 45 PERIODS

REFERENCES

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

9. Smejkal G. B. And Lazarev A. V. “Separation methods in Proteomics”. CRC Press, 2006
10. Twyman R. M. “Principles of Proteomics”. Taylor & Francis. 2004

BO5002 HUMAN PHYSIOLOGY AND DRUG METABOLISM L T P C
3 0 0 3

OBJECTIVES

- To provide fundamental knowledge of human physiology, drug metabolism and biotransformation of drug in human body.

UNIT I FOUNDATIONS OF PHYSIOLOGY AND OVERALL PHYSIOLOGY CONCEPTS 12

ANS, CNS, Cardiovascular system, Gastrointestinal system, Muscle and skeletal system, excretory system

UNIT II GROWTH AND METABOLISM 12

Chemical & Physical Foundations – Homeostatic control – neural & endocrine mechanisms– Transport across cell membranes 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 6

Biotransformation of drugs; Enzymes responsible for bio-transformations; Microsomal and non-microsomal, mechanisms.

UNIT V MODEL IN DRUG METABOLISM 7

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

OUTCOME

- This course work will provide basic understanding of human physiology and drugmetabolism which will enable the student to understand how the body functions and thephysiological mechanisms that operate to maintain homeostasis.

REFERENCES

1. Ganong W.F., “Review of Medical Physiology”, 23rdEdition, Prentice Hall, 2013. 11thEdition, Mc-Graw Hill, 2005.

2. Vander A.J., Sherman, J.H. and Luciano, D.S. “Human Physiology”, Mcgraw-Hill, 13th Edition.
3. Carola, R., Harley, J.P. and Noback, C.R., ‘Human Anatomy and Physiology’, 2ndEdition,
4. Guyton, A.C., “Text Book of Medical Physiology”, 9thEdition, Harcourt Brace &Co., 1996.
5. Ross and Wilson, “Human Anatomy and Physiology”, ELBS 12thEdition. 2014.
6. Goodman &Gilman, Laurence L Brunton, “The Pharmacological Basis Of Therapeutics”,
7. Woolf, Thomas F. “Handbook of Drug Metabolism”. Marcel Dekker, 1999.
Mcgraw Hill, 1992

BO5003 BIOCONJUGATE TECHNOLOGY AND APPLICATIONS L T P C
3 0 0 3

OBJECTIVES

- The course will provide advanced theoretical knowledge on Bio conjugate technologies in Biopharmaceutical Applications

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 – Photo-reactive chemical reactions.

UNIT III BIOCONJUGATE REAGENTS 9

Zero length cross linkers – Homo-bifunctional cross linkers –Hetero-bifunctional cross linkers– Trifunctional cross linkers – Cleavable reagent systems – tags and probes.

UNIT IV ENZYME AND NUCLEIC ACID MODIFICATION AND CONJUGATION 9

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

UNIT V BIOCONJUGATE APLICATIONS 9

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

TOTAL : 45 PERIODS

OUTCOME

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

REFERENCE

1. Christ of M. Niemeyer, "Bioconjugation Protocols: Strategies and Methods", Humana Press, 2004.
2. Hermanson, G.T. “Bioconjugate Techniques”. Academic Press 3rd Edition, 2013.
3. Mo Aslam, Alastair Dent "Bioconjugation: Protein Coupling", Stockton Press, 1998.
4. Shan S. Wong, David M. Jameson, "Chemistry of Protein and Nucleic Acid Cross-Linking and Conjugation", 2nd Edition, 2012, CRC Press.

BO5004 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 to explore thisknowledge for practical applications

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 flavonollactone 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, B1, B2, B6, B12and Folicacid. Chemistry and structural elucidation of uric acid, interrelation between caffeine,theophylline and theobromine. Classification and application of flavanoids (hespiridineetc)

UNIT V MOLECULES FROM NATURAL SOURCES 9

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

TOTAL : 45 PERIODS

OUTCOME

- At end of the course work students will appreciate the importance of natural compounds as novel drugentity for the development of newer drugs.

REFERENCES

1. Evans, W.C., 'Trease and Evans Pharmacognosy', 16thEdition 2009.
2. Kokate, C.K. "Pharmacognosy", 29thEdition, Niraliprakashan, 2004.
3. N. R. Krishnaswamy, "Chemistry of Natural Products", Universities Press, 2010, 2nd Edition
4. Sujata V. Bhat, B.A. Nagasampagi, Meenakshi Sivakumar. "Chemistry of Natural Products",Springer Science & Business Media, 2005

BO5005 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 and advanced understanding of drug interactions.

UNIT I INTRODUCTION TO MOLECULAR MEDICINE 9

Organization of the Human Genome, Chromosomes and Genes – Recombinant DNA and Genetic Techniques – Transcriptional Control of Gene Expression – transmission of Human Genetic Disease – Human Genome Project – Cell Cycle Oncogenes and Tumor suppressor Genes – Molecular Diagnostic Testing – Genetic Counseling – Transgenic Mice as Models of Disease, Introduction to gene therapy.

UNIT II CARDIOLOGY 9

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

UNIT III PULMONOLOGY 9

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

UNIT IV ENDOCRINOLOGY 9

Mechanisms of Hormone Action – Diabetes Mellitus – Pituitary Function and Neoplasia GrowthHormone Deficiency Disorders – Thyroid Disorders – Disorders of the parathyroid Gland – CongenitalAdrenal Hyperplasia – Adrenal Disease – Multiple Endocrine NeoplasiaType 2 – MolecularMechanisms of Hypoglycemia Associated with increased Insulin Production.

UNIT V NEPHROLOGY 9

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

TOTAL : 45 PERIODS

OUTCOME

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

REFERENCES

1. Jameson, J. L., Francis, S.C., “Principles of Molecular Medicine”, Humana Press, 1998.
2. Ross, D.W. “Introduction to Molecular Medicine”, 3rd Edition, Springer, 2002.
3. Ross, D.W. “Introduction to Oncogenes and Molecular Medicine”,Springer, 1998.
4. Pasternak, J.J. “An Introduction to Human Molecular Genetics”, 2nd Edition, Wiley Liss,2005.
5. Strachan, Tom and Andrew P. Read. “Human Molecular Genetics, Garland Science,4thEdition, 2010..

BO5006 CLINICAL TRIALS AND BIOETHICS L T P C
3 0 0 3

OBJECTIVES

- The course will provide Fundamental ethical to advanced clinical trial management including drug development and trial planning; Project management in clinical trials; Consent and data protection; Quality assurance and governance.

UNIT I INTRODUCTION TO CLINICAL TRIALS 9

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

UNIT II REGULATIONS OF CLINICAL TRIALS 9

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

UNIT III MANAGEMENT AND ETHICS OF CLINICAL TRIALS 9

Project management in clinical trials - principles of project management; Application in clinical trial management; Risk assessment; Research ethics and Bioethics - Principles of research ethics; Ethical issues in clinical trials; Use of humans in Scientific Experiment; 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 INFORMED CONSENT 9

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

UNIT V QUALITY CONTROL AND GUIDELINES 9

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

TOTAL: 45 PERIODS

OUTCOME

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

REFERENCES

1. Lee, Chi-Jen et al, “Clinical Trials or Drugs and Biopharmaceuticals.” CRC / Taylor &Francis,2011.
2. Matoren, Gary M. “The Clinical Research Process In The Pharmaceutical Industry. “Marcel Dekker, 1984.
3. Lawrence M.Friedman et al, “Fundamentals of Clinical Trials”, Mosby,1996
4. Curtis L Meinert et al, “Clinical Trials - Design Conduct and Analysis”,Oxford University Press 1986.

BO5007 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

UNIT I BASICS OF ENZYMES AS BIOCATALYSIS 9

Introduction to enzymes, Classification, Sources, Mechanism of enzyme action. Strategies of purification of enzymes, criteria of purity, molecular weight determination and characterization of enzymes , Enzymesof biological importance - Acetylcholinesterase, angiotensin converting enzyme (ACE), ACE Inhibitors,HMG CoA reductase inhibitors, pseudocholinesterase, 5 -nucleotidase (5NT), glucose-6-phosphatedehydrogenase (GPD), Kisoforms, immune reactivetrypsinogen (IRT) and chymotrypsin; amylaseIsoenzymes.

UNIT II KINETICS OF ENZYME ACTION 9

Methods for investigating the kinetics of Enzyme catalyzedreactions – Initial velocity Studies,Estimation of Michaelis-Menten parameters, Effect of pH and temperature on enzyme activity, kinetics of inhibition. Modeling of rate equations for single and 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 of immobilized enzyme reactors; applications of immobilized enzyme technology, Economic argument for immobilization

UNIT IV ENZYMES IN FUNCTIONAL GROUP TRANSFORMATION 9

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

UNIT V ENZYMATIC TRANSFORMATION 9

Reaction engineering for enzyme-catalyzed biotransformations. Catalytic antibodies. Biocatalysts from extreme Thermophilic and Hyperthermophilicmicroorganisms(extremozymes). The design and construction of novel enzymes, artificial enzymes, Biotransformation of drugs (hydroxylation of Steroids), Host Guest Complexation chemistry, enzyme design using steroid templates, enzymes for production of drugs, fine chemicals and chiral intermediates.

TOTAL: 45 PERIODS

OUTCOME

- The students will acquire knowledge in all aspect of Biocatalysis, enzyme kinetics and immobilization.
- The enzymatic transformation will give theoretical idea about drug biotransformation.

REFERENCES

1. Bailey J.E. &Ollis, D.F. Biochemical Engineering Fundamentals, 2nd Ed., McGraw Hill,1986
2. Blanch, H.W., Clark, D.S. Biochemical Engineering, Marcel Dekker, 1997
3. Faber, Kurt “Biotransformations in organic chemistry: A Textbook” 5thEdition. Springer2008.
4. "Hydrolases in Organic Synthesis (Regio and Stereo Selective biotransformations)”. U. T.Bornscheuer and R. J. Kazlauskas. Willey-VCH.
5. Karlheinz Drauz, Harald Gröger, Oliver May,“Enzyme catalysis in organic synthesis”3rd Edition,Wiley VCH, 2012.
6. Lee, James M. Biochemical Engineering, PHI, USA, 1982.
7. "Stereoselective biocatalysis” R.N. Patel. Marcel Dekker. (ISBN: 0-8247- 8282-8)

BO5008 PROTEIN ENGINEERING AND INDUSTRIAL APPLICATIONS L T P C

3 0 0 3

OBJECTIVES

- To provide advanced knowledge of proteins and their structure function relationship, essential for future pharmaceutical technology.

UNIT I INTRODUCTION 6

Amino acids, primary structure of proteins, amino acid composition, industrial significance, primary structure determination by chemical methods including automated sequencing and by gene sequencing, significance of primary structure determination, peptide synthesis, secondary structure and super secondary structures

UNIT II PROTEIN ARCHITECTURE 6

Tertiary structure of proteins, types of proteins, domains, quaternary structure, protein complexes, protein-protein interactions

UNIT III STRUCTURE-FUNCTION RELATIONSHIP 15

DNA-binding proteins: prokaryotic transcription factors, Helix-turn-Helix motif in DNA binding, Trp repressor, Eucaryotic transcription factors, Zn fingers, helix-turn helix motifs in homeodomain, Leucine zippers

Membrane proteins: General characteristics, Transmembrane segments, prediction, bacteriorhodopsin and Photosynthetic reaction center

Immunoglobulins: IgG Light chain and heavy chain architecture,

Abzymes and Enzymes: Serine proteases, understanding catalytic design by engineering trypsin, chymotrypsin and elastase, substrate assisted catalysis other commercial applications.

UNIT IV PROTEIN ENGINEERING METHODS 9

Protein engineering methods, amino acid side chain reactions, chemical modification of proteins, site-directed mutagenesis, posttranslational modifications and engineering.

UNIT V INDUSTRIAL APPLICATIONS OF PROTEIN ENGINEERING 9

Examples of industrial protein engineering applications Engineering of serine proteases, engineering of antibodies, engineering of proteins for thermal stability, engineering of proteins for preventing aggregation, His-tagged proteins in purification, engineering proteins for secretion, de novo protein synthesis.

TOTAL: 45 PERIODS

OUTCOME

- On completion of the course, students will learn the functional characteristics of various types of proteins and engineering of proteins for production of new protein pharmaceutics.

REFERENCES

1. Alberghina, L. “Protein Engineering in Industrial Biotechnology”. Harwood Academic Publications, 2000.
2. Branden C. and Tooze J., “Introduction to Protein Structure”, 2nd Edition, Garland Publishing,1999.
3. Creighton, T.E. “Proteins: Structure and Molecular Properties”, 2nd Edition, W.H.Freeman, 1993

4. Holland, I Barry et al., “ABC Proteins: From Bacteria to Man”. Academic Press Elsevier, 2003.
5. Moody P.C.E. and Wilkinson A.J. “Protein Engineering”. IRL Press, Oxford, 1990.
6. Rees, A.R., Sternberg, M.J.E. and Wetzel, R. “Protein Engineering: A Practical Approach”. IRL Press, 1992
7. Voet, D. and Voet, G., “Biochemistry”. 4th Edition, John Wiley and Sons, 2001.
8. Whitford, David “Proteins: Structure and Function”. John Wiley & Sons, 2005.

BO5009 MICROBIAL TECHNOLOGY L T P C
3 0 0 3

OBJECTIVES

- To provide fundamental knowledge of pharmaceutical microbiology and microorganisms associated with the manufacture of pharmaceuticals

UNIT I BIOLOGY OF MICROORGANISMS 9

Introduction – Microscopy - Structure and form of the bacterial cell – size, shape and structure of the cell wall and cytoplasmic membrane - Appendages to the bacterial cell - Capsules and slime - Bacterial spore - process of spore formation – Germination of spores – Toxins produced by bacteria –Yeasts and moulds - Introduction – Structure- Cell wall - Properties of selected fungi - Saccharomyces cerevisiae, Neurospora crassa, Penicillium, Aspergillus, Epidermophyton, Microsporum and Trichophyton

UNIT II INFECTIOUS DISEASES 9

Introduction - Spread of infection - Common source infections – Principles of microbial pathogenicity and epidemiology - Properties of selected pathogens – Staphylococcus, Streptococcus, Neisseria, Clostridium, Listeria, Pseudomonas, Vibrio, Yersinia, Haemophilus, Escherichia, Salmonella, Shigella, Proteus, Helicobacter- Chlamydia, Rickettsia, Mycobacterium – Spirochetes – Borrelia, Treponema and Leptospira, Candida and Cryptococcus

UNIT III ANTIBIOTICS AND OTHER ANTIMICROBIAL AGENTS 9

Antibiotics – definition, sources and types of antibiotics – penicillins, cephalosporins – Lincomycins, Tetracyclines, Rifamycins and Macrolides – Structure- activity relationships – Pharmacokinetic properties – Antifungals - synthetic antimicrobial agents – Mechanism of action – Bacterial resistance to antibiotics – Antivirals – Methisazone, nucleoside analogues – interferons – Clinical uses of antimicrobial agents

UNIT IV MICROBIAL ASPECTS OF PHARMACEUTICAL PROCESSING 9

Ecology of microorganisms as it affects the pharmaceutical industry - Microbial spoilage and preservation of pharmaceutical products - Contamination of non-sterile pharmaceuticals in hospitals and community Environments - Principles and practice of sterilization - Sterilization control and sterility assurance - Sterile pharmaceutical products - Factory and hospital hygiene and good manufacturing practice

UNIT V BIOCATALYST TECHNOLOGY 9

Advantages and disadvantages of biocatalysis over chemical catalysis; Different types of biocatalysis: Microbial, enzymatic and immobilized system of biocatalysis; Current industrial biocatalysis; Biocatalysis with different enzymes: Lipase, amidase/ aminopeptidase, Acylase, Hydantoinase, lyases, Oxidoreductase, Nitrilase, Epoxide hydrolase, Hydroxylase, Aldolases, Decarboxylase;

TOTAL : 45 PERIODS

OUTCOME

- The students would have learnt various aspects of pharmaceutical microbiology include the research and development of anti-infective agents, the use of microorganisms to detect mutagenic and carcinogenic activity in prospective drugs, and the use of microorganisms in the manufacture of pharmaceutical products

REFERENCES

1. Biocatalyst for Industry. JONATHAN S. DORDICK. 1991 Springer Science &Business Media New York.
2. Frank Austen, K., Burakoff, S.J., Fred Rosen, Terry B. Strom, Therapeutic Immunology, Blackwell Science, Boston, 3rd Edition, 2006.
3. Hugo, W.B. and Russell, A.D. Pharmaceutical Microbiology – 7th Edition – Blackwell Science Ltd. Oxford, 2004.
4. Mims C.A. The Pathogenesis of Infectious Disease,3rd Edition - London: Academic Press,1987.
5. Thomas J. Kindt, Barbara A. Osborne, Richard A. Goldsby, Kuby Immunology, W.H., Freeman & Co, San Francisco, 6th Rev. Edition, 2006

BO5010 PHARMACOLOGY L T P C

3 0 0 3

OBJECTIVES

- The objective of the course is to provide advanced knowledge in detail on the pharmacology of drugs and toxicology.

UNIT I INTRODUCTION TO PHARMACOLOGY 9

Sources of drugs, dosage forms and routes of drug administration, pharmacodynamics. Combined effect of drugs, factors modifying drug action, tolerance and dependence. Basic and clinical pharmacokinetics. Adverse drug reactions. Drug interactions, Bioassay of drugs and biological standardization, Overview of drug discovery and development.

UNIT II DRUGS ACTING ON THE HAEMOPOIETIC SYSTEM AND CARDIOVASCULAR SYSTEM 9

Haematinics, Anticoagulants, vitamin K and haemostatic agents, Fibrinolytic and anti-platelet drugs, Blood plasma volume expanders. Histamine, 5-hydroxytryptamine, Prostaglandins and

their antagonists, cardiac glycosides and other drugs for congestive heart failure, antiarrythmatic, antianginal, anti-ischemic, and anti hypertensive drugs.

UNIT III PHARMACOLOGY OF DRUGS ACTING ON GASTROINTESTINAL TRACT AND ENDOCRINE SYSTEM 9

Antacids, anti-secretory and anti-ulcer drugs; Laxatives and Anti-diarrhoeal drugs; Appetite stimulants and suppressants; Emetics and anti-emetics; Hypothalamic and pituitary hormones, Thyroid hormones and anti-thyroid drugs, Parathormone, Calcitonin and Vitamin D, Insulin, Oral hypoglycemic agents and glucagon. ACTH and corticosteroids, Androgens and anabolic steroids, Estrogens, progesterone and oral contraceptives, Drugs acting on the uterus;

UNIT IV CHEMOTHERAPY 9

General principles of chemotherapy; Sulfonamides; Antibiotics – Penicillins, Cephalosporins, Chloramphenicol, macrolides, Quinolones, fluroquinolones and other antibiotics; Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, urinary tract infections and sexually transmitted diseases; Chemotherapy of malignancy and immune suppressive agents.

UNIT V MOLECULAR PHARMACOLOGY AND PRINCIPLES OF TOXICOLOGY 9

Classification of neurotransmitters and receptors, mechanism of action, receptor activation and signal transduction with special reference to CNS, Definition of poison, general principles of treatment of poisoning, Heavy metals and heavy metal antagonists, OECD guidelines for testing acute, sub-acute, and chronic toxicity, genotoxicity, carcinogenicity, teratogenicity and mutagenicity of drugs and chemicals.

TOTAL : 45 PERIODS

OUTCOME

After the completion of course, the student will able to

1. Identify typical examples of drugs which are used to restore physiological functions.
2. Understand the systemic effect of drug action on human body.
3. Recognize the fundamental principles used in pharmacology and toxicology of drugs for academic and industrial research.

REFERENCES

1. Goodman and Gilman's, "The Pharmacological Basis of Therapeutics".12th Edition, 2010.
2. Katzung, B.G., Trevor AJ. Basic and Clinical Pharmacology, Prentice Hall International. 12thEdition, 2011.
3. Kulkarni S K, Handbook of Experimental Pharmacology, 4th Edition, 2012.
4. Rang, M.P, Dale M.M, Reter J.M- Pharmacology.8th Edition, 2016.
5. Satoskar, "Pharmacology and Pharmacotherapeutics", 24th Edition, 2015.
6. Tripathi, K.D. "Medical Pharmacology", 7th Edition, 2016.

BO5011 ADVANCED TECHNOLOGIES IN OMICS SCIENCES L T P C
3 0 0 3

OBJECTIVES

- The course intends to give advanced theoretical knowledge on Microarrays, Next GenerationDNA sequencing and Protein profiling.

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 IN BIOLOGICALS 9

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

TOTAL : 45 PERIODS

OUTCOME:

- The students will acquire knowledge in advanced molecular methods to carry out academic and industrial research

REFERENCES

1. Causton H. C., Quackenbush J., And Brazma A. (2004) “A Beginner’s Guide Microarray. Gene Expression Data Analysis”. Blackwell Publishing.
2. Hoffman E. D. And Stroobant V. (2007) “Mass Spectrometry – Principles And Applications”. John Wiley & Sons Ltd, 3rd Edition
3. Muller H. J. And Roder T. (2006) “Microarrays”. Elsevier Academic Press
4. O’connor C. D. And Hames B. D. (2008) “Proteomics”. Scion Publishing Ltd.

5. Rinaldis E. D. And Lahm A (2007) “DNA Microarrays”. Horizon Bioscience. Causton,H.C
6. Schena M. (2000) “DNA Microarrays - A Practical Approach”. Oxford University Press.
7. Schena M. (2005) “Protein Microarrays”. Jones And Bartlett Publishers

BO5012 METABOLIC ENGINEERING L T P C
3 0 0 3

OBJECTIVES

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

UNIT I METABOLIC FLUX ANALYSIS 9

Introduction to metabolic engineering, comprehensive models of cellular reactions with stoichiometryand reaction rates; metabolic flux analysis of exactly/over/under determined systems. Shadowprice, sensitivity analysis.

UNIT II TOOLS FOR EXPERIMENTALLY DETERMINING FLUX THROUGHPATHWAY 9

Monitoring and measuring the metabolome, Methods for the experimental determination of metabolicfluxes by isotope labeling metabolic fluxes using various separation –analytical techniques. GC-MS formetabolic flux analysis, genome wide technologies: DNA /phenotypic microarrays and proteomics.

UNIT III CONSTRAINT BASED GENOMIC SCALE METABOLIC MODEL 9

Development of Genomic scale metabolic model, *Insilico* Cells: studying genotype-phenotyperelationships using constraint-based models, case studies inE.coli, S.cerevisiaemetabolicnetwork 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 summation theorems, Determination of flux control coefficients. Multi-substrate enzyme kinetics,engineering multifunctional enzyme systems for optimal conversion, and a multi scale approach for the predictive modeling of metabolic regulation.

UNIT V CASE STUDIES IN METABOLIC ENGINEERING 9

Metabolic engineering examples for bio-fuel, bio-plastic and green chemical synthesis. Study of genome scale model in various system for the production of green chemicals using software tools. Validation of the model with experimental parameters.

TOTAL: 45 PERIODS

OUTCOME

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

REFERENCES

1. Cortassa, S. et al, "An Introduction to Metabolic and Cellular Engineering", WorldScientific Publishing, 2002.
2. Kholodenko, Boris N andH. V. Westerhoff "Metabolic Engineering in the Post GenomicEra", Horizon Bioscience, 2004.
3. Lee, S .Y. and Papoutsakis, E.T. "Metabolic Engineering". Marcel Dekker, 1998.
4. Nielsen, J. and Villadsen, J. "Bioreaction Engineering Principles". Springer, 3rd Edition, 1994.
5. Scheper, T. "Metabolic Engineering" Vol 73 (Advances inBiochemical EngineeringBiotechnology) Springer, 2001.
6. Smolke, Christiana D., "The Metabolic Pathway Engineering Handbook Fundamentals", CRC Press Taylor &Francis, 2010.
7. Stephanopoulos, G.N. "Metabolic Engineering: Principles andMethodologies". AcademicPress / Elsevier, 3rd Edition, 1998.
8. Voit, E.O. "Computational Analysis of Biochemical Systems: A Practical Guide forBiochemists andMolecular Biologists". Cambridge University Press, 2000.

BO5013 PHARMACOGENOMICS L T P C

3 0 0 3

OBJECTIVES

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

UNIT I INTRODUCTION TO PHARMACOGENOMICS 9

Pharmacogenetics-The roots of pharmacogenomics, Genetic drug response profiles, the effect of drugs on Gene expression, pharmacogenomics in drug discovery and drug development.

UNIT II THE HUMAN GENOME 9

Expressed sequence Tags (EST) and computational biology, Microbial genomics, computational analysis of whole genomes, Genomic differences that affect the outcome of host pathogen interactions: future of whole genome-based pharmacological science.

UNIT III ASSOCIATION STUDIES IN PHARMACOGENOMICS 9

Viability and ADR in drug response: contribution of genetic factor, Multiple inherited genetic factors influence the outcome of drug treatments, Plasma binding proteins, Drug targets.

UNIT IV GENOMICS APPLICATIONS FOR DRUG ACTION AND TOXICITY 9

Genomics, Proteomics; applications in 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 target s leading to change in the ligand binding pocket.

TOTAL : 45 PERIODS

OUTCOME

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

REFERENCE

1. Chabrabarthy, Chiranjb and Bhattacharyya, Atane, “Pharmacogenomics: An Approach to New Drugs Development”, 2004.
2. Federico Innocent, "Pharmacogenomics: Methods and Protocols", Springer, 2009
3. Licinio, Julio and Ma-Li Wong, “Pharmacogenomics: The Search for the Individualized Therapies”, Wiley-VCH, 2002
4. Loralie J. Langman, Amitava Dasgupta, "Pharmacogenomics in Clinical Therapeutics", John Wiley & Sons, 2012.
5. Othstein, Mark, A. “Pharmacogenomics: Social, Ethical and Clinical Dimensions”, Wiley-Liss, 2003

BO5014 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.

UNIT I FUNDAMENTALS ON RATIONAL DRUG DESIGN 9

Various approaches in drug discovery process – conventional versus rational, drug targets, lead identification; Principles of ligand chemistry – lead optimization, pharmacophores, bio-isosteres, principles of ligand chemistry such as configuration, conformation, chirality, isosteric replacement; Parameters of ligand design such as –Physiochemical, geometric, conformational, topological, partitional, steric, stereochemical and electronic properties of drug molecules;

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

Introduction to molecular docking (including methods and scoring functions), denovo pharmacophore elucidation/ drug design for structurally well-defined receptor targets from case studies (Eg. HIV protease inhibition, ACE inhibition); Principles of macromolecule-ligand docking, docking algorithms, AUTODOCK; Molecular dynamic simulations, relative energy, energy minimization methods, ligand binding free energy calculations (both simulation and empirical methods), intermolecular interactions, forces related to drug binding, force-field calculation including solvation, role of solubility in drug binding and pKa, Poisson-Boltzmann Surface Area (PBSA), AMBER,GROMOS and GROMACS.

UNIT III COMBINATORIAL AND SYNTHETIC PEPTIDE LIBRARIES 9

Combinatorial Chemistry in drug development, Biopolymers as natural libraries, Selection and evolution of expression genetic libraries, Combinatorial assembly of antibody genes, Molecular solutions to Combinatorial problems, Solid-Phase peptide synthesis, Peptide on pins, Other iterative 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 analytical biochemistry used in HTS (photometry, purification, electrophoresis, kinetic assay, radioisotopes, immunoassay,HTS FACS based assays). Assay design for HTS and statistical treatment of the results for decision.

UNIT V GENETIC BASED TOOLS IN DRUG DISCOVERY PROCESS 9

Basic of gene silencing, transgenic worms in drug screening; designing siRNAs, Types of RNAi Screens – Loss of Function screens (LOF), Synthetic Lethal screen, Mini-clonogenic RNAi screen; optimizing, and implementing high-throughput siRNA genomic screening for the discovery of survival genes and novel drug targets, siRNA HTS Screening for identification of targeted pathways in biological systems.

TOTAL : 45 PERIODS

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.

REFERENCES

1. Block J.H. and Beale, J.M., 'Wilson &Gisvolds Text Book of Organic Medicinal and Pharmaceutical Chemistry', 11th Edition, Lippincott Williams &Wilkins, 2004
2. Fassina, G. "Combinatorial Chemistry and Technologies: Methods and Applications", 2ndEdition, CRC Press, 2005
3. GROMOS And GROMACS Manuals , 2014.
4. Janzen W. P. "High Throughput Screening: Methods and Protocols". Humana Press. 2002
5. Leach, AR, "Molecular Modeling&Drug Design", 2ndEdition, John Willy, 2000

6. Murray, K.J. “Principles and Practice of High Throughput Screening”. Blackwell ScientificPublishers, 2004.
7. Williams, D.A. and Lemke, T.L., "Foye's Principles for Medicinal Chemistry” 5thEdition, Lippincott, Williams &Wilkins, 2002.
8. "Wilson and Gisvold’s Textbook of Organic Medicinal and Pharmaceutical Chemistry”.10thEdition, Lippincott-Raven Publisher, 1998.
9. Ye, S., and Day, I.N.M. “Microarrays and Microplates: Applications in BiomedicalSciences”. BIOS 2003

BO5015 NANOBIOTECHNOLOGY L T P C
3 0 0 3

OBJECTIVES

- The ‘Nanobiotechnology’ course aims to provide fundamental concepts of nanotechnology and advanced knowledge on the application of nanotechnology to biological sciences including nanomedicine.

UNIT I NANOSCALE AND NANOBIOTECHNOLOGY 9

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

UNIT II FABRICATION AND CHARACTERIZATION OF NANOMATERIALS 9

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

UNIT III PROPERTIES AND MEASUREMENT OF NANOMATERIALS 9

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

UNIT IV NANOBIOLOGY AND BIOCONJUGATION OF NANOMATERIALS 9

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

UNIT V NANO DRUG DELIVERY AND NANOMEDICINE 9

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

TOTAL : 45 PERIODS

OUTCOMES

- The students would have learned the physicochemical properties of nanomaterials; the unique changes that happen at nanoscale; nanoscale view of the natural biomolecular processes; synthesis, modification, and characterization of nanomaterials; and application of Nanomaterials to biological problems including nanomedicine

REFERENCES

1. "Bio-Nanotechnology_ Concepts and Applications". Madhuri Sharon, Maheshwar Sharon,Sunil Pandey and Goldie Oza, Ane Books Pvt Ltd, 1st Edition 2012
2. "Microscopy Techniques forMaterial Science". A. R. Clarke andC. N. Eberhardt (Editors) CRC Press. 1st Edition, 2002.
3. "Nanobiotechnology Protocols (Methods In Molecular Biology)" by Sandra J Rosenthaland David W. W Right , Humana Press; 1 Edition, 2005.
4. "Nanobiotechnology: Bioinspired Devices andMaterials oftheFuture"by Odedshoseyovand Ilan Levy, Humana Press; 1 Edition 2007.
5. "Nanobiotechnology: Concepts, Applications and Perspectives", Christ ofM. Niemeyer(Editor), Chad A. Mirkin (Editor), Wiley-VCH; 1 Edition, 2004.

BO5016 RESEARCH AND RESEARCH METHODOLOGY IN BIOTECNOLOGY L T P C
3 0 0 3

OBJECTIVES

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

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 ofResearch; 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 ANDMETHODOLOGY 9

Precision, accuracy, sensitivity and specificity; major experimental 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 negativeresults, 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

OUTCOME

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

REFERENCES

1. "Biochemical Calculations: How to Solve Mathematical Problems in General Biochemistry",2ndEdition, Irwin H. Segel, John Wiley &Sons Publishers, Inc, 1976.
2. "Essentials of Research Design and Methodology" Geoffrey R.Marczyk, David DeMatteo, David Festinger, John Wiley &Sons Publishers, Inc , 2005.
3. "Guide to Publishing aScientific Paper", Ann M. Korner, 2004, Bioscript Press
4. S Janarthanan, "Practical Biotechnology: Methods and Protocols" Orient Blackswan 2007

BO5017 ADVANCE ANALYTICAL TECHNIQUES FOR BIOLOGIST L T P C

3 0 0 3

OBJECTIVE

- To enable students to acquire knowledge in various advanced analytical techniques used in the screening of pharmaceutical agents.

UNIT I UV-VISIBLE SPECTROSCOPY 9

Brief introduction of spectroscopy, EMR and principle of absorptions by molecule. The absorption law – Beer's and Lambert's law, limitations and chromospheres concept,Theory of electronic transition theory, choice of solvent and solvent effects, modern instrumentation – design and working principle. Applications of UV-Visible spectroscopy (various qualitative and quantitative methods), Woodward – Fischer rules for calculating absorption maximum.

UNIT II IR SPECTROSCOPY AND THERMAL METHODS OF ANALYSIS 9

Infrared radiation, theory of IR absorption by a molecule, vibrational frequency and factors influencing vibrational frequency, rotational degrees of freedoms, transmission/absorption

modes, types of bands, instrumentation and sampling techniques, interpretation of spectra, applications in pharmaceuticals.FT-IR-theory and applications, Attenuated Total Reflectance (ATR).Instrumentation and applications of thermal methods - Thermo Gravimetric Analysis (TGA),Differential Scanning Calorimetry (DSC), Differential Thermal Analysis (DTA) and Thermo Mechanical Analysis (TMA).

UNIT III NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY 9

Basic theory of NMR/PMR, excitation/emission process and instrumentation. solvents, reference compound, scale of measurement, shielding/deshielding; chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling and shift reagents, proton exchange reactions, FT-NMR, 2D -NMR, NMDR, NOE, NOESY, COSY and applications in pharmaceuticals, spectral interpretations, C13 NMR, Natural abundance, C13-NMR, its role in structural applications.

UNIT IV MASS SPECTROMETRY 9

Basic principles, instrumentation and ionization methods; precursor ion/product ion production and fragmentation pattern; atmospheric pressure ionization (API), Chemical ionization (CI), Field Ionization (FI), Fast Atom Bombardment (FAB), Matrix assisted laser desorption ionization(MALDI), Time of Flight (TOF), hybridization with other techniques, and interpretation of mass spectrum and applications in pharmaceuticals.

UNIT V CHROMATOGRAPHIC METHODS 9

Classification of chromatographic methods on mechanism of separation: High Performance Liquid Chromatography : Principle, instrumentation, solvents, packing materials and applications in pharmaceuticals; Gas Chromatography: principle, theory, column operations, instrumentation, derivatisation methods and applications in pharmaceuticals; HPTLC and Super Critical Fluid Chromatography (SFC): Theory, instrumentation, elution techniques and pharmaceutical applications; Principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Iso-electric focusing (IEF) and applications.

TOTAL: 45 PERIODS

OUTCOME

- The student would have learnt various advanced analytical techniques for identification, separation, purification and quantification of pharmaceutical agents from various biological sources.

REFERENCES

1. "Chromatographic Analysis of Pharmaceuticals", John A. Adamovics, 2ndedition,1996.
2. "HPTLC – Quantitative Analysis of Pharmaceutical Formulations"– P. D. Sethi,1990.
3. "Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography"– P. D. Sethi, Dilip Charegaonkar, 2nd Edition, 2014.
4. "Instrumental Methods of Analysis"– Hobert H. Willard, 7th Edition, 1992.
5. "Instrumental Methods of Chemical Analysis"– B. K. Sharma - 9th Edition,2000.
6. "Liquid Chromatography – Mass Spectrometry", W.M.A.Niessen, J. Van Der Greef,Vol.58,2006.

7. "Organic Chemistry"by I.L.Finar Vol. II – 5thedition, 1956
8. "Organic Spectroscopy"– William Kemp, 3rd Edition, 1991.
9. "Pharmaceutical Analysis – Modern Methods"– Part A, Part B, James W.Munson– 2001.
10. "Practical Pharmaceutical Chemistry", Part II, A. H. Beckett &J. B. Stenlake, 4th Edition,2015.
11. "Principles of Instrumental Analysis" by Donglas A. Skoog, James, J. Leary, 4th Edition,1992.
12. "Spectrometric Identification of Organic Compounds", Robert. M. Silverstein Et Al, 8thdition, 2014.
13. "Spectroscopy of Organic Compounds" by P. S. Kalsi, 2007.
14. "Techniques and Practice of Chromatography"– Raymond P. W. Scott, Vol. 70,2003.
15. "Vogel's Text Book ofQuantitative Chemical Analysis", 6th Edition, 2004.

BO5018 HERBAL DRUG DEVELOPMENT AND STANDARDIZATION L T P C
3 0 0 3

OBJECTIVE

- To enable students to acquire theoretical knowledge in herbal drug development and understanding the theoretical principles of standardization.

UNIT I GENERAL METHODS OF PROCESSING OF HERBS 9

Definition, sources, identification and authentication of herbs - Different methods of processing of herbs like collection, harvesting and garbling - packing and storage conditions - Methods of drying – Natural and artificial drying methods, with their merits and demerits.

UNIT II EXTRACTION METHODS 9

Principles of extraction and selection of suitable extraction method - Different methods of extraction including maceration, percolation, hot continuous extraction, pilot-scale extraction and supercritical fluid extraction with their merits and demerits - Purification and recovery of solvents

UNIT III STANDARDIZATION OF HERBAL RAW MATERIALS AND EXTRACTS 9

Standardization of herbal raw materials, including pharmacognostical, physical, chemical and biological methods with examples - Standardization of herbal extracts, physical, chemical and spectral analysis - Qualitative and Quantitative estimation of active principles from standardized extracts by HPTLC - Biological standardization -Pharmacological screening of herbal extracts and Microbiological evaluation of herbal extracts - Toxicity studies of herbal extracts.

UNIT IV ISOLATION AND ESTIMATION OF PHYTOCONSTITUENTS 9

Different methods for isolation and estimation of phytoconstituents from the following drugs (with special emphasis on HPLC and HPTLC): Hypericin / Hyperforin from Hypericum species - Forskoline from Coleus forskoli - Catechins from Green tea - L-hydroxy citric acid from Garcinia combogia - L-Dopa from Mucuna pruriens. Andrographolides from Andrographis paniculata -

Alicin from Garlic - Piperine from Piper nigram / Piper longum - Bacosides from Bacopa monnieri - Berberine from Berberis aristata etc.

UNIT V HERBAL DRUG FORMULATION AND QUALITY CONTROL 9

Selection of herbal ingredients. Analysis of herbal ingredients. Different dosage forms of herbal drugs. Evaluation of different dosage forms. Stability studies of herbal formulations.

TOTAL: 45 PERIODS

OUTCOME

- The students would have learnt various herbal formulation, processing and standardization of herbal extracts and estimation of phytoconstituents.

REFERENCES

1. Barn, J.N., "Biological Standardization", Oxford University Press, London, 2ndEdition, 1950.
2. Choudhary,, R.D., "Herbal Drug Industry", Eastern Publisher, New Delhi, 1stEdition, 2004
3. Kokate, C.K., Purohit, Gokhlae, "Text Book of Pharmacognosy", Nirali Prakashan, New Delhi, 4th Edition, 1996.
4. Mukarjee, P.K., "Quality Control of Herbal Drug"s, Business Horizons Pharmaceutical Publisher, 1st Edition New Delhi, 2002.
5. Wagner, H., Bladt, S., "Plant Drug Analysis", Springer, New York, 2ndEdition, 1996.

BO5019 ADVANCED CANCER BIOLOGY L T P C

3 0 0 3

OBJECTIVES

- To develop fundamental concepts of cancer identification, etiology and epidemiology. To know the signaling pathways and their relation to cancer. To understand the cellular and molecular basis of current strategies for cancer prevention and treatment.

UNIT I INTRODUCTION TO CANCER BIOLOGY 9

Regulation of cell cycle; mutations that cause changes in signal molecules; Apoptosis and caspases; Cancer Epidemiology; Chemical and Radiation Carcinogenesis

UNIT II MOLECULAR ASPECTS OF CANCER 9

Signal targets and cancer; activation of kinases; Oncogenes; detection of oncogenes; retroviruses and oncogenes; Oncogenes/proto oncogene activity; Tumor Suppressor Genes; Growth factors related to transformation.

UNIT III METASTASIS & ANGIOGENESIS 9

Three step theory of invasion; basement membrane disruption; metastatic cascade; Angiogenesis; Tumor Progression and Metastasis; Cell Proliferation and Cell Death

UNIT IV CANCER MANAGEMENT 9

Different forms of therapy- chemotherapy; radiation therapy; immunotherapy- engineered monoclonal antibodies and vaccines; use of signal targets towards therapy of cancer; Gene therapy; pharmacology of Anti-neoplastic agents.

UNIT V CANCER MARKERS AND ITS DETECTION 9

Diagnostic Tests; Detection using biochemical assays; tumor markers; ideal markers; risk markers; diagnostic markers; prediction of aggressiveness of cancer; molecular tools for early diagnosis of cancer; Hormones and cancer; Immune system and cancer.

TOTAL: 45 PERIODS

OUTCOME

- To understand the cellular mechanisms and cell cycle and acquire knowledge on molecular aspects of Cancer

REFERENCES:

1. B.Pardee And G. Stein, "The Biology and Treatment of Cancer", John Wiley &Sons Inc., Publishers, 2009
2. J. Gabriel, "The Biology of Cancer", 2ndEdition, John Wiley &Sons Inc., Publishers, 2007
3. M.R. Alison, "The Cancer Handbook", Nature Publishing Groups, 2003
4. R. W. Ruddon, "Cancer Biology", Oxford University Press, 2007
5. S. Pelengaris And M. Khan, "The Molecular Biology of Cancer", John Wiley &Sons Inc., Publishers, 2009

BO5020 ENTREPRENEURSHIP AND INTELLECTUAL PROPERTY RIGHTS LT P C
3 0 0 3

OBJECTIVE

- To enable students to acquire knowledge in Entrepreneurship and IPR and understanding the rules and regulations.

UNIT I ENTREPRENEURSHIP 10

Definition, functions and kinds of entrepreneurs, intrapreneur-entrepreneurship and economic development, entrepreneurial competencies-traits, developing competencies, project identification, selection and financing. Project report- content and significance, Planning Commission's guidelines for formulating project reports-methods of project appraisals.

UNIT II INTRODUCTION TO INTELLECTUAL PROPERTY 10

Types of Intellectual property (IP): Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications, Protection of GMOs IPas a factor in R&D; IPs of relevance to Biotechnology Agreements and Treaties History of GATT & TRIPS Agreement; Madrid Agreement; Hague Agreement; WIPO Treaties; Budapest Treaty; PCT; Indian Patent Act 1970 & recent amendments Case Studies

UNIT III BASICS OF PATENTS AND CONCEPT OF PRIOR ART 8

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 PATENTING PROCEDURES 7

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 BIOENTREPRENEURSHIP AND BIOSAFETY 10

Introduction; Historical Background; Introduction to Biological Safety Cabinets; PrimaryContainment 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 Cartegana Protocol.

TOTAL : 45 PERIODS

OUTCOME

- The students would have learnt various law, rules and regulations in IPR, Patent, procedure and student became a Entrepreneur.

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
3. M.M.S Karki, "Intellectual Property Rights: Basic Concepts", Atlantic 2009.
4. S.S.Kanka "Entrepreneurship Development", S.Chand and Co, New Delhi 1997.
5. Solution Pvt. Ltd., 2007

BO5091 TISSUE ENGINEERING AND REGENERATIVE MEDICINE L T P C

3 0 0 3

OBJECTIVES

- The course intends to give advanced theoretical knowledge on tissue engineering, Stemcells and its biological applications

UNIT I INTRODUCTION 9

Introduction to tissue engineering: Basic definition; current scope of development; use intherapeutics, cells as therapeutic agents, cell numbers and growth rates, measurement of cell

characteristics morphology, number viability, motility and functions. Measurement of tissue characteristics, appearance, cellular component, ECM component, mechanical measurements and physical properties.

UNIT II TISSUE ARCHITECTURE 9

Tissue types and Tissue components, Tissue repair, Basic wound healing events, Applications of growth factors: Role of VEGF. Angiogenesis, Basic properties, Cell-Matrix & Cell-Cell Interactions, Control of cell migration in tissue engineering.

UNIT III BIOMATERIALS 9

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

UNIT IV BASIC BIOLOGY OF STEM CELLS 9

Stem Cells : Introduction, Types & sources of stem cell with characteristics: hematopoietic differentiation pathway, Potency and plasticity of stem cells, sources, embryonic stemcells, hematopoietic and mesenchymal stem cells, Stem Cell markers, FACS analysis, Differentiation, Stem cell systems- Liver, neuronal stem cells, cancer stem cells, induced pluripotent stem cells.

UNIT V CLINICAL APPLICATIONS 9

Stem cell therapy, Molecular therapy, *In-vitro* organogenesis, Neurodegenrative diseases,spinal cord injury, heart disease, diabetes, burns and skin ulcers, muscular dystrophy, orthopedic applications, Stem cells and Gene therapy, Physiological models, tissue engineering therapies, product characterization, components, safety, efficacy. Preservation –freezing and drying. Patent protection and regulation of tissue-engineered products, ethical issues.

TOTAL: 45 PERIODS

OUTCOME

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

REFERENCES

1. Artech House, Inc Publications Naggy N.Habib, M.Y. Levicar, , L. G. Jiao,and N. Fisk, “Stem Cell Repair And Regeneration, Volume-2,Imperial College Press.2007
2. Bernard N. Kennedy (Editor). Stem “CellTransplantation, Tissue Engineering, and Cancer Applications”New York: Nova Science Publishers, 2008.
3. Bernhard O.Palsson,Sangeeta N.Bhatia,“Tissue Engineering” Pearson Publishers 2009.
4. J. J. Mao, G. Vunjak-Novakovic et al (Eds), “Translational Approaches In TissueEngineering & Regenrative Medicine” 2008,
5. Meyer, U.; Meyer, Th.; Handschel, J.; Wiesmann, H.P.Fundamentals of TissueEngineering and Regenerative Medicine.2009.
6. R. Lanza, I. Weissman, J. Thomson, and R. Pedersen, “Handbook Of Stem Cells, Two-Volume, Volume 1-2: Volume 1-Embryonic Stem Cells; Volume 2-Adult & Fetal StemCells”, Academic Press,2004.

7. R. Lanza, J. Gearhart etal (Eds)," Essential of Stem Cell Biology",ElsevierAcademic Press.2006.
8. Raphael Gorodetsky, Richard Schäfer.."Stem CellbasedTissue Repair"Cambridge: Rsc Publishing, 2011.

BO5021 NOVEL DRUG DELIVERY SYSTEM L T P C
3 0 0 3

OBJECTIVE

- The course intends to give advanced knowledge about various Novel drug delivery systems

UNIT I SUSTAINED RELEASE DRUG DELIVERY SYSTEMS (SRDDS) 9

Introduction - rationale of SRDDS - advantages and disadvantages of SRDDS - factors influencing the design and performances of SRDDS – physicochemical properties of a drug influencing design and performance - biological factors influencing design and performance of SRDDS - routes of drug administration of SRDDS - micro encapsulation - different micro-encapsulation processes, - advantages - disadvantages and applications - polymers used in SRDDS – classification and applications in formulation - system design for rate–controlled drug delivery - feedback - regulated drug delivery systems, in vitro and in - vivo evaluation of controlled released drug delivery

UNIT II PARENTERAL CONTROLLED RELEASE DRUG DELIVERY SYSTEMS 9

Approaches for injectable controlled release formulations - development of injectable controlled - release formulations – long-acting penicillin preparations – long-acting Insulin preparations - long acting steroid preparations and long-acting contraceptive preparations - approaches and applications of implantable drug delivery systems

UNIT III ORAL CONTROLLED RELEASE SYSTEMS 9

Design and development of oral controlled-release drug administration - dissolution controlled – diffusion-controlled - membrane permeation controlled - osmotic pressure controlled - gel diffusion-controlled - pH controlled - ion - exchange controlled delivery systems - prolongation of GI retention of oral drug delivery system

UNIT IV TRANSDERMAL AND MUCOADHESIVE DRUG DELIVERY SYSTEMS 10

Permeation through skin, factors affecting permeation, basic components of TDDS, formulation approaches used in development of TDDS and their evaluation, permeation enhancers - buccal drug delivery system - structure of oral mucosa - trans-mucosal permeability - mucosal membrane modules - permeability enhancers – in vitro and in vivo methods for buccal absorption - buccal strips - nasal drug delivery systems - physiology of nose - fundamentals of nasal absorption - distribution of drug in the nasal cavity - enhancement of absorption – in vitro and in vivo methods for determination of nasal absorption - applications of nasal drug delivery systems - pulmonary drug delivery system and its applications

UNIT V OCULAR AND TARGETED DRUG DELIVERY SYSTEM 8

Preparation and evaluation of ocular controlled drug delivery systems - ophthalmic inserts and *in-situ* gels – targeted drug delivery systems – concepts - targeting of drugs through nanoparticles, liposome - resealed erythrocytes – microspheres - magnetic microspheres and monoclonal antibodies - brief study of colon targeting

TOTAL:45 PERIODS

OUTCOME

- The student will acquire knowledge about various Novel drug delivery systems and chemical, biophysical and biological factors that impact on targeted, sustained and controlled drug delivery systems

REFERENCES

1. Jain, N.K, "Controlled andNovel Drug Delivery", CBS, New Delhi, 1stEdition, 1997 (Reprint In 2001).
2. Mathiowitz, E., "Encyclopedia ofControlled Delivery", John Wiley, New York, 3rd Edition, 2007.
3. Remington, J.P, Gennaro, A.R., "Remington's Pharmaceutical Sciences", Mack Publishers, Easton, 17th Edition, 1985.
4. Robinson, J.R., Lee, V.H.L, "Controlled Drug Delivery - Fundamentals And Applications", Marcel Decker, 2ndEdition, 1987.
5. Vyas, S.P., Khar, R.K., "Controlled Drug Delivery - Concepts andAdvances", Vallabh Prakashan, New Delhi, 1st Edition, 2002.

BO5022 DOWNSTREAM PROCESSING L T P C

3 0 0 3

OBJECTIVE:

- To develop an understanding of concepts in efficient separation of biomolecules (proteins, peptides, oligosaccharides, DNA, etc) and particularly with relevance to pharmaceuticals

UNIT I INTRODUCTION TO BIOSEPARATION 7

Fundamentals and concepts in bioseperation technology. Characterization and analysis of fermentation broth, Physical methods of structure determination of biomolecules, Guidelines to recombinant protein purification.

UNIT II ISOLATION OF PRODUCTS 10

Extraction – theory and practice: Aqueous two phase extraction, supercritical fluid extraction. Precipitation techniques: salts, solvents, polymers (PEG). Membrane based separation – Microfiltration, Ultrafiltration, reverse osmosis, dialysis.

UNIT III CHROMATOGRAPHY FOR BIOSEPARATION 12

Theory, practice and selection of media for – gel-filtration chromatography, Ion exchange chromatography, Hydrophobic interaction chromatography, reverse phase chromatography,

Affinity chromatography – Metal affinity chromatography, dye affinity chromatography, immunosorbent affinity chromatography & Expanded bed chromatography. Scale-up criteria for chromatography, calculation of no. of theoretical plates and design. Electrophoresis separation.

UNIT IV FINAL POLISHING AND CASE STUDIES 10

Freeze drying, lyophilization, spray drying and crystallization. Case studies on purification of: cephalosporin, aspartic acid, Recombinant Streptokinase, Monoclonal antibodies, Tissue plasminogen activator, Taq polymerase, Insulin. Case studies of product recovery economics.

UNIT V ADVANCED BIOSEPARATIONS 6

Recent trends in bioseparations, perevaporation, reverse miceller extraction, super critical fluid extraction spin base, magnetic separation and their application, case studies of product purification and recovery.

TOTAL: 45 PERIODS

OUTCOME:

- Students get skills to understand the various principles involved in protein purification. Understand the characterization of various bio-molecules. Understand the principles involved in various chromatography techniques

REFERENCE:

1. B. Sivasankar, “Bioseparations: Principles and Technique”, Prentice-Hall Of India Pvt.Ltd, 2007.
2. Bailey, J. E. and Ollis, D. F. "Biochemical Engineering Fundamentals" 2ndEdition, Mcgraw-Hill, New Delhi,1986.
3. Belter, P. A, Cussler, E. L, And Hu, W. “Bioseparations: Downstream Processing for Biotechnology”. 1987.
4. Harrison R.G.; Todd P.; Rudge S.R. and Petrides D.P. “Bio separations Science and Engineering”, Oxford Press,2003.
5. Janson, Jan-Christer, Ed. “Protein Purification: Principles, High Resolution Methods and Applications”.Wiley. 2011.
6. Jenkins, R. O (Ed.) (1992) “Product Recovery in Bioprocess Technology – Biotechnology by Open Learning Series”, Butterworth-Heinemann.
7. Ladhish, M.R. “Bio separation Engineering, Principles, Practice and Economics”, Wiley Interscience, 2001.
8. Scopes R.K.“Protein Purification – Principles And Practice”, Narosa Publishers, 1994.

BO5092 BIOMATERIALS L T P C

3 0 0 3

OBJECTIVES

- To know the classification of biomaterial, their bulk and surface properties and characterization to prepare the students to find a place in biomedical field .To learn the various biological responses to the materials and biomechanics .To have an exposure

on the clinical context of their use, manufacturing processes and testing, cost, sterilization, packaging and regulatory issues.

UNIT I INTRODUCTION AND CLASSIFICATION 9

Introduction and classifications; Metals: different types, properties and interaction with the tissue, Polymers: classification and properties, Ceramics: Types, properties and interactions with the tissue, Composites: matrix and reinforcing agents/fillers and properties, Cell adhesion, host- tissue reactions. Tissue derived biomaterials: Structure and properties of collagen and collagen-rich tissues, Biotechnology of collagen, design of resorbable collagen-based medical implants soft.

UNIT II BULK AND SURFACE CHARACTERIZATION 9

Bulk Characterization: XRD, FT-IR, SEM, energy dispersive X-ray (EDX), DSC, TGA, dielectric analysis (DEA); Surface analysis: XPS, SIMS, AES, surface enhances Raman spectroscopy (SERS), AFM/STM; Structural properties of tissues-bone, teeth and elastic tissues, Effects of sterilization on material properties.

UNIT III TESTING 9

Biocompatibility: blood and tissue compatibility; degradation of biomaterials in biological environment, toxicity tests, sensitization, carcinogenicity, mutagenicity and special tests; In vitro and In vivo testing, implant associated infections, biocompatibility enhancement using carona discharge and plasma processes, surface coatings; Ethical considerations, good manufacturing practice, standards, Regulatory issues.

UNIT IV TISSUE REPLACEMENT IMPLANTS WITH BIOMATERIALS 9

Tissue replacements, sutures, surgical tapes, adhesive, percutaneous and skin implants, maxillofacial augmentation, blood interfacing implants, hard tissue replacement implants, internal fracture fixation devices, Joint replacements.

UNIT V ARTIFICIAL ORGANS WITH BIOMATERIALS 9

Artificial heart, prosthetic cardiac valves, limb prosthesis, externally powered limb prosthesis, Dental implants.

TOTAL: 45 PERIODS

OUTCOME

- To select biomaterial for organ replacement and temporary body implant Design, analytical, problem solving, technical judgment skills

REFERENCES:

1. D. Shi , Ed., “Biomaterials and Tissue Engineering”, Berlin, New York: Springer, 2004.
2. Joon Park, D.B. Joseph and Boca Ration, “Biomaterials: Principles and Applications”, CRC, Press, 2003.
3. Kay C. Dee, David A. Puleo and Rena Bizios, “An Introduction to Tissue-Biomaterial Interactions”, John wiley, 2002.

4. L. Hench and J. Jones, “Biomaterials, Artificial Organs and Tissue Engineering”, Woodhead Publishing in Materials, 2002.
5. Ratner, B. D., et al, (eds.), “Biomaterials Science: An Introduction to Materials in Medicine”, Academic Press, 2004
6. Saltzman W M, “Tissue Engineering: Engineering Principles for the Design of Replacement Organs and Tissues”, Oxford University Press, 2004.