MASTER OF SCIENCE IN PHARMACEUTICAL BIOTECHNOLOGY

The course of study and scheme of examination

1.Name of the course: M.Sc., Pharmaceutical Biotechnology

2.Medium of instructions: English

3. Choice Based Credit System (CBCS)

Choice based credit system is a flexible system of learning. "Credit" defines the quantum of contents / syllabi prescribed for a course and determine the number of hours of instruction required.

The CBCS has unique features such as enhan ced learning opportunities, ability to match students scholastic need and aspirations, inter institution transferability of students, part completion of an academic program in the institution of enrollment and part completion in specialized and recognized institution, improvement in educational quality and excellence, flexibility for working students to complete Programme over an extended time and standardization and comparability of educational programs across the country.

4.The preamble of the syllabus

Master of Science (M.Sc.) in Biotechnology, the curricula, and course content were designed to meet the standards of UGC-CSIR (NET) and (SLET) examinations. The choice- based credit system of learning develops a strong base in the core subject and specializes in the disciplines of his / her liking and abilities and develops an in-depth understanding of various aspects of Biotechnology. The students develop experimental skills, design, and implementation of novel synthetic methods, and develop the aptitude for academic and professional skills, by acquiring basic concepts for structural elucidation with hyphenated techniques, and understanding the fundamental biological process and rationale of the computer. The project introduced in the curriculum will motivate the students to pursue research and entrepreneurial skill development.

> Examination Pattern: Time allotted: Theory – 03Hrs. & Practical – 04 hrs

	External Marks	Internal Marks	Total marks
Theory	75	25	100
Practical	75	25	100

Marks allotted for university examination:

Marks distribution for internals:

	Test	seminars	Assignment	Total marks
Theory	15	05	05	25

	Test	Record	Total marks
Practical	10	15	25

Pattern of question paper (theory):

The course of study and the scheme of Examination – Department of Biotechnology

Study Compor	ients	ins.	Cre		Maximum Marks		
Course Title		hrs / week		Title of the Paper	CIA	Uni.	Total
S	EMESTER I					Exam	
Core	Paper -1	5	4	Pharmaceutical Biotechnology -	25	75	100
Core	Paper -2	5	4	Advance in Recombinant DNA Technology	25	75	100
Core	Paper -3	5 4Fundamentals of Microbiology, Molecular Biology and Chemical Engineering		25	75	100	
	Internal Ele	ctive for	same	major students (Choose any one)			
Core Elective	Elective – I	3		A.Chemistry of Natural product. B.Toxicology and environmental chemistry. C.Basic fundamentals in clinical	25	75	100
Practical -I		5	3	trails. A.	25	75	100
Practical -II		5	3	3A.		75	100
Value Added course	VAC-1	2		A.Social and preventive pharmacy . B.Pharma marketing management. C.Pharmaceutical Regulatory science.	25	75	100
		30	23				
SI	EMESTER II				CIA	Uni. Exam	Tota
Core	Paper – 4	4	4	Research Methodology	25	75	100
Core	Paper – 5	4	4	Pharmaceutical Biotechnology - II	25	75	100
Core	Paper – 6	4	4	Advanced Analytical Tools in Biotechnology	25	75	100
Core	Paper - 7	4	4	Physical chemistry concepts in Pharmaceuticals.	25	75	100
	Internal Ele	ctive for	same	major students (Choose any one)			
Core Elective	Elective -II	2	2	A.Organic Chemistry - I B.Unit operation in Bio process. C.Advanced Pharmaceutical Biotechnology	25	75	100

Practical -III				A. Pharmaceutical Biotechnology - I	25	75	100
Practical -IV		4		A. Pharmaceutical Biotechnology - II	25	75	100
External Elective fo	r other major stu	idents (I	nter/n	nulti-disciplinary papers) (Choose a	any on	e)	
Open Elective	Open Elective - I	2	2	A.Biochemical engineering fundamentals. B.Biotechnology in Pharmaceutical science. C.Analysis, Diagnostics and cell based screening.	25	75	100
Compulsory Paper	Paper -8	2 2 A. Introduction to cancer Biology		25	75	100	
		30	28				

Study Com		ins. hrs / week	Credit		Max Mar	cimum •ks	
Course Title						Uni.	Total
	SEMESTER 1	III			CIA	Exam	
Core	Paper -9	4	4	A. Bio process and fermentation technology	25	75	100
Core	Paper –10	4	4	4B. Pharmaceuticals biotechnology and drug design.		75	100
Core	Paper – 11	4	4	C. Chemistry of drug I	25	75	100
Core	Paper -12	4	4	D. Chemistry of drug - II	25	75	100
	Inter	nal Elect	ive for	same major students (Choose any	y on	e)	
Core Elective	Elective -III	3	3	 A. Drug design and drug development. B.Basic of Pharmaceuticals 	25	75	100
				Chemistry. C.Molecular Pharmaceutics nanotechnology and targeted DDS.			
External E	lective for other	major stu	idents	(Inter/multi-disciplinary papers) (Cho	ose any	one)
Open Elective	Open Elective - II	2		A.Separation Techniques. B.Biostatistics. C.Immunology and Immuno technology.	25	75	100
Practical - V		5	3	A.Pharmaceutical Biotechnology	25	75	100
Practical - VI		4	3	A.Pharmaceutical Biotechnology	25	75	100
*MOOC Courses			2				100
*USRR		30	2 31				100

	SEMESTER	IV			CIA	Uni. Exam	Total
Core	Paper -13	4	4	A. Molecular modelling and drug designing.	25	75	100
Core Elective	Elective -IV	3	3	A.Research methodology, IPR and Bioethics.B. Bioinformatics and computational biotechnology.C. Biological Evaluation of drugs therapy.	25	75	100
Core Project 23 5		Project with viva voice	(75	100 Project 5 viva)	100		
		30 120	12 94		725	2275	2900

Extra credits for * MOOC course = 2 * USSR Project = 2

SEMESTER I

PAPER 1: Pharmaceutical Biotechnology

Paper code:

Subject: M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of pharmaceutical biotechnology and also the advances in Recombinant DNA technology and also the fundamentals of microbiology, molecular biology and chemical engineering and also about the research methodology.

Course Objectives

1.To learn the basic concept of Pharmaceutical Industry, fermentation technology.

2.To learn the concepts of cloning vectors, gene therapy in genetic disease.

3. To develop knowledge on fundamentals of microbiology , molecular biology and chemical engineering .

4.To understand the basic of research methodologies

5.To develop a piece of knowledge in advanced analytical tools in biotechnology.

Course Out Comes

1.After completing unit 1, the students will be able to identify the concept in technology in pharmaceutical industry.

2.After completing unit 2, the students will be able to know about the methods in genetic

manipulation ..

3. After completing unit 3, the students will be know about the fermentation technology.

4. After Completing unit 4, the students will be know about the Scale up process and fermentation process.

5. After completing unit 5, the students will be know about the productivity of fermented products.

6. After completing unit 6, the students will be know about the fermentation process.

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Biotechnology in the Pharmaceutical Industry (Pre-biotechnology products, impact of biotechnology, post-biotechnology products: biologics and bio-pharmaceuticals)	12 hours
Unit-II	Genetic manipulation methods	12 hours
Unit-III	Fermentation technology	12 hours
Unit-IV	Scale-up process (Inoculum: preparation and development of inoculum for industrial fermentation, optimization of the fermentation process (pH, temperature, and oxygen requirements, Determination of the optimized feeding regimen and biomass quantification	
Unit-V	Improvement of selected microorganism with increased productivity of the fermented products	12 hours
Unit-VI	Fermentation process: Batch and continuous fermentation and fermenters, Fermentation products in Pharmaceutical industry: Antibodies, Therapeutic proteins, Vitamins, Amino acids, Monoclonal Antibodies)	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	Μ	Μ	М	S	S	S
CO2	М	М	М	S	S	Μ	S	S	М	М
CO3	М	М	М	S	S	S	S	Μ	М	М
CO4	S	S	S	М	Μ	Μ	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium,

L - Low

SEMESTER I

PAPER 2: Advances in Recombinant DNA Technology

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of Vectors, and also the cloning strategies and also the transformation of E.coli and also the detection of nucleic acid sequence and also the genomic DNA libraries.

Course Objectives

1.To learn the basic concept of cloning vectors and introduction to Plasmids.

2.To learn the cloning strategies and PCR products. .

3.To develop knowledge on Chemical transformation and Electroporation.

- 4.To understand the basic labeling and detection of nucleic acid sequence
- 5..To develop a piece of knowledge in genomic DNA library and genetic disease.

Course Out Comes

6.After completing unit 1, the students will be able to identify the vectors and Plasmids.

7.After completing unit 2, the students will be able to know about the Cloning strategies

8.After completing unit 3, the students will be know about the Chemical transformation and Electroporation

9. After completing unit 4, the students will be Selection and screening of recombinant transformants

10.After completing unit 5, the students will be detection of nucleic acid sequences

11.After completing unit 6, the students will be Genomic DNA libraries

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Vectors: Cloning vectors: Plasmids, Lambda phages, single stranded DNA vectors (M13, fd, f1); Cosmids, Phasmids and Phagemids, YACs, BACs, PACs; Plant Transformation vectors: Introduction to Ti, Ri plasmids and BIBACs; Expression Vectors for high level protein expression	,
Unit-II	Cloning strategies: Vector preparation and diverse cloning strategies viz. blunt end cloning, directional cloning, TA-cloning of PCR products, linkers and adaptors based cloning methodologies	
Unit-III	E coli transformation: Chemical transformation and Electroporation	12 hours
Unit-IV	Selection and screening of recombinant transformants: Introduction to marker and reporter genes and selection strategies	12 hours
Unit-V	Labeling and detection of nucleic acid sequences: End-Labeling (3'- and 5'-), Random priming and Nick translation using radioactive non-radioactive labeling techniques	

Unit-VI	Genomic DNA libraries: Procedures for Partial, Representative,	05 hours					
	Enriched, Large-insert DNA libraries, Half-arm cloning, cDNA libraries:						
	Prominent Adapters/Linkers based directional cloning						
Unit - VII	Unit - VII Gene therapy for genetic diseases						
	Total Teaching hours						

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	Μ	М	S	S	S
CO2	М	М	М	S	S	Μ	S	S	М	М
CO3	М	М	М	S	S	S	S	Μ	М	М
CO4	S	S	S	М	Μ	М	S	S	М	S
CO5	М	М	М	S	Μ	S	Μ	Μ	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

SEMESTER I

PAPER 3: Fundamentals of Microbiology, Molecular Biology and Chemical Engineering.

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of fundamentals of microbiology, molecular biology and chemical engineering.

Course Objectives

- 1. To learn about the microbes, cultivation and preservation of micro organisms.
- 2. To learn the structure of DNA, RNA.
- 3. To develop knowledge on Recombinant DNA technology
- 4. To understand the basic of fundamental chemical engineering
- 5. .To develop a piece of knowledge based on products on scale up of operations.

Course Out Comes

6. After completing unit 1, the students will be able to know about the microbes, importance of

sterilization and methods of sterilization.

7. After completing unit 2, the students will be able to know about the genome organization and overview of transcription in prokaryotes and eukaryotes.

8. After completing unit 3, the students will be know about the fundamental of chemical engineering .

9. After completing unit 4, the students will be know about the Agricultural and Environmental Microbiology

10. After completing unit 5, the students will be know about the Industrial Microbiology

11. After completing unit 6, the students will be know about the medicinal microbiology .

Unit	i. Remembering	ii.	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
		Understanding				
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Fundamentals of Microbiology : Microbes – types, size shape and arrangement of bacterial cells, Nutritional requirements – Commor ingredients, culture media and types of media, Sterilization – Importance and various methods of sterilization, Cultivation and Preservation of microorganisms – Isolation, pure culture, study of cultural characteristics and methods of preservation, Measurement of microbial growth – Total count and viable count methods, Preparation of microscopic observation – Compound microscope stains used, simple staining, differential staining and special staining techniques.	h - 1 6 1 2
Unit-II	Fundamentals of Molecular Biology : The beginnings of Molecular biology, The structure of DNA, Genome organization: Prokaryotes and Eukaryotes., The Versatility of RNA: Types of RNA and their role DNA replication: Prokaryotic and Eukaryotic, Overview of Transcription in prokaryotes and eukaryotes, From Gene to Protein Genetic code and Translation, Recombinant DNA technology: Ar introduction, molecular cloning and some tools for analyzing gene expression	

Unit-III	Fundamentals of Chemical Engineering : Transport phenomenon, Heat transfer, Mass transfer, Process and equipment design for various operations in processing of pharmaceutical biotechnology based products and discussions on scale-up of operations; Prediction of freezing, heating and drying times	
Unit-IV	Microbiology of soil, Air and Aquatic Microbiology, Biofertilizer, Plant endophytes, Microbes in bioremediation and biocontrol agents.	12 hours
Unit-V	Microbial processes using yeasts and bacteria (production of alcohol, vinegar, cheese), Microbes as source of protein (SCP), gelatin agents (alginate, xanthin, agar agar) Microbial insecticides, Enzymes from Microbes (amylase, protease), Useful products from microorganisms using recombinant DNA technology (vaccines and antibiotics).	
Unit-VI	Medical Microbiology: Normal microflora, common diseases caused by microbes-pathogenesis, symptoms, diagnosis, treatment, prevention	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Reference Book:

1. Stainer R.Y., Ingraham J.L., "General Microbiology"- 5 th Edition Mc.Millan Press, 2010.

2. Madigan, Martinko, Parker, Brock's, "Biology of Microorganisms" - 10th Edition, Prentice Hall, Pearson Education, 2003.

3. Prescot and Dunn, "Industrial Microbiology"-Agribios India, 2002.

4. J. Salle, "Fundamental Principles of Bacteriology" – 7 th Edition, Tata Macgraw Hill, 2007.

5. E Alcamo I "Fundamentals of Microbiology"6th Ed, Jones & Bartlet, Pub. 2001. 6. Prescott,

Harley & Klein, "Microbiology" -7 th Edition, WCB/McGraw Hill, Int. Edition, 2008.

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	Μ	S	М	S	М	Μ	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

SEMESTER I

CORE ELECTIVE 1: Chemistry of Natural products

Paper code: Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 3

Aim: To enable the students to understand the basic concepts of Structural elucidation by classical methods.

Course Objectives

1.To learn about the terpenoids

2.To learn about the Brevicomin, Eucomin and Eucomol.

3.To develop knowledge on Terpenoids

4.To understand the basic of Alkaloids

5.. To develop a piece of knowledge Introduction to Biogenesis and Biosynthesis.

Course Out Comes

6.After completing unit 1, the students will be able to know about Structural elucidation by classical methods.

7.After completing unit 2, the students will be able to know about the Structure elucidation of terpenoids.

8. After completing unit 3, the students will be know about the Structure elucidation of Brevicomin, Eucomin and Eucomol.

9.After completing unit 4, the students will be know about the Synthesis of selected natural products

10.After completing unit 5, the students will be know about the Introduction to Biogenesis and Biosynthesis.

11.After completing unit 6, the students will be know about the Natural products used as colour pigments

Unit	i. Remembering	ii.	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
		Understanding				
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Structural elucidation by classical methods: Terpenoids: Cedrene, Alkaloids: Morphine, Steroids: Cholesterol	12 hours
Unit- II	.Structure elucidation of terpenoids: □ and □ vetinones and hormones Cecropia JH by combination of physical and chemical methods.	12 hours
	Structure elucidation of Brevicomin, Eucomin and Eucomol by spectral methods.	12 hours
Unit- IV	Synthesis of selected natural products: Terpenoids: Longifolene (Corey Synthesis), Alkaloids: Reserpine (Woodward Synthesis), Hormones: Cecropia JH (Edward Synthesis), Antibiotics: Cephalosporin (Woodward synthesis), Prostaglandins: Prostaglandins-E2 (Corey Synthesis).	
Unit- V	Introduction to Biogenesis and Biosynthesis. Biogenesis of secondary metabolites: Application of tracer techniques in evaluation of biogenetic pathways of secondary metabolites	
Unit- VI	Natural products used as colour pigments, excipients, biopolymers, photosensitizing agents, flavours, biofuels.	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Reference Book:

- 1) K. Natkanish, Natural product chemistry, Acad Press.
- 2) I. Fleming, Selected organic synthesis, John Wiley and Sons.

- 4) D.R. Dalton, The Alkaloids, Marcel Dekker.
- 5) I.L. Finar, Stereochemistry and Chemistry of natural products.
- 6) Agrawal O.P., Chemistry of Organic Natural Product, Goel Publication House, UP.
- 7) E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company.
- 8) Pridham J B, Swain T, Biosynthetic pathway in higher plants, Academic Press, New York.
- 9) Bardon and Oils, Comprehensive organic Chemistry.
- 10) J. Corey and Xue-men Cheng, Wiley Interscience.
- 11) K.C. Nicolau and E.J. Sorensen, Classics in Total Synthesis

Mapping with Programme Outcomes

ſ	Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
	CO1	S	S	S	М	М	М	М	S	S	S
Ī	CO2	М	М	М	S	S	М	S	S	М	Μ
ľ	CO3	М	Μ	Μ	S	S	S	S	Μ	Μ	Μ
Ī	CO4	S	S	S	М	М	М	S	S	М	S
ĺ	CO5	М	Μ	Μ	S	М	S	Μ	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

SEMESTER I

CORE ELECTIVE 2 : Toxicology and Environmental Chemistry Subject:M.sc Environmental Biotechnology

Paper code:

Hours/Week: 5Credits: 3

Aim: To enable the students to understand the basic concepts of Definition ,principles of toxicology

Course Objectives

1.To learn about the Carcinogenicity, mutagenicity, teratogenicity.

2.To learn about the Toxic chemicals in the environment.

3.To develop knowledge on Green house effect

4.To understand the basic of Sources of water pollution

5.. To develop a piece of knowledge fertility management of soils

Course Out Comes

6.After completing unit 1, the students will be able to know about Basic principles of toxicology,Preclinical valuation of drugs.

7.After completing unit 2, the students will be able to know about Toxic chemicals in the environment.

8. After completing unit 3, the students will be know about classification of air pollutants

9. After completing unit 4, the students will be know about Water quality parameters

10. After completing unit 5, the students will be know about Sources of water pollution

11. After completing unit 6, the students will be know about Soil and Soil Pollution

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
	Course Contents	
Unit I	Definition and types of toxicology, Basic principles of toxicology, Carcinogenicity, mutagenicity, teratogenicity, acute, sub acute and chronic toxicity. Pre-clinical valuation of drugs. Drugs and pregnancy. Drug addiction and drug habit/ dependence drug abuse, physical dependence, psychological dependence. (8L) Detailed toxicity(mild/moderate/severe toxicology wherever applicable) and treatment of drugs such as salicylates/ paracetamol, opium, quinine, ethyl alcohol, nicotine/digitalis, barbiturates, etc.	
Unit-II	Toxic chemicals in the environment, impact of toxic chemicals on enzymes. Biochemical effects of arsenic, lead mercury, cadmium, carbon monoxide, sulphurdioxide, pesticides and carcinogens.	12 hours
Unit-III	Green house effect, Acid rain, Ozone hole phenomenon, Source & toxic effects of Pb and Cd. Sources-stationary and transportation sources of air pollution, classification of air pollutants-sources, effects and control of CO, SO2, NOx, HC as gaseous pollutants, suspended particulate matter aerosols, photochemical air pollution, sampling of air pollutants-gaseous and particulate, analysis of air pollutants, stack monitoring.	
Unit-IV	Water quality parameters and their analysis-colour, temperature, transparency, turbidity, pH, TDS, DO, free CO2, total hardness, Ca & Mg hardness, alkalionity, chloride, sulphate, ammonia, nitrite, NO3, organic N. phosphorus (total inorganic-organic), silica, BOD, COD, DO.	
Unit-V	Sources of water pollution-soild waste, industrial, agricultural, oil, radiaoactive waste, thermal pollution, sampling of water pollutants.	12 hours
Unit-VI	Definition, component of soil, fertility management of soils, soil sediment analysis-physical and chemical parameters. Soil pollution-sources, detrimental effects and control.	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Reference Book:

1. A.K. De, Environment Chemistry, Wiley Eastern Ltd., New Delhi.

2. R.K. Trivedy and P.K. Goel, Chemical and Biological Methods for Water Pollution Studies, Environment Publications, Karad (India)

- 3. S.L. Chopra and J.S. Kanwar, Analytical Agricultural Chemistry, Kalyani Publishers, New Delhi.
- 4) Thad Godish, Air Quality.
- 4. S.P. Mahajan, Pollution control in Process Industries, 1994.
- 5. Harry Freeman, Hazardous Waste Minimization, 1990.
- 6. Metcalf and Eddy, Waste Water Engineering, 1993
- 8. Herfindale.E.T. and Hirschmann, J.L.; Clinical Pharmacy and Therapeutics.

Co	OS	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CC	D1	S	S	S	М	М	М	М	S	S	S
CC	02	М	М	М	S	S	М	S	S	М	М
CC	03	М	М	М	S	S	S	S	М	М	М
CC	04	S	S	S	М	М	М	S	S	М	S
CC)5	М	М	М	S	М	S	М	М	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

SEMESTER I

CORE ELECTIVE 3 : Basic Fundamentals in Clinical Trials

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 3

Aim: To enable the students to understand the basic concepts of clinical trial in new drug developments.

Course Objectives

1.To learn about the Introduction to clinical Trial

2.To learn about the .supervision of ethics

3.To develop knowledge on Designs used in clinical trials

4.To understand the basic of Stakeholders of clinical trials

5.. To develop a piece of knowledge Good Clinical Practice.

Course Out Comes

- 6.After completing unit 1, the students will be able to know about Introduction to clinical Trial
- 7. After completing unit 2, the students will be able to know about Ethical issues in clinical trials
- 8.After completing unit 3, the students will be know about Clinical trial design
- 9.After completing unit 4, the students will be know about Clinical trial protocol Development
- 10. After completing unit 5, the students will be know about Good Clinical Practice

11. After completing unit 6, the students will be know about Management of Clinical trials.

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
						C C
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units		Teaching hours
	Course Contents	
Unit I	History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments	12 hours
Unit-II	.Principal, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report.	
Unit-III	Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls.	
Unit-IV	Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial.	
Unit-V	Concept, importance, and GCP guidelines including ICH guidelines	12 hours
Unit-VI	Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Reference Book:

- 1. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, Elsevier
- 2. Davidson's Principles of Internal Medicine, Vol-I And II, 14 th Edition, Mc Graw-Hill
- 3. Harrison's Principle And Practice Of Medicine, 18 th Edition, Churchill, Livingston, London
- 4. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
- 5. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics
- 6. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice,

Chapman and Hall, New York.

	Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
	CO1	S	S	S	М	М	М	М	S	S	S
ſ	CO2	М	М	М	S	S	М	S	S	М	М
	CO3	М	М	М	S	S	S	S	М	М	М
	CO4	S	S	S	М	М	М	S	S	М	S
	CO5	М	М	М	S	М	S	М	М	S	S

Mapping with Programme Outcomes

 $PO-Programme\ Outcome,\ CO-Course\ outcome,\ S-Strong,\ M-Medium,\ L-Low$

PRACTICALS - I (3 credits)

Microbiology & Molecular Biology Laboratory

1. Study of bacteria, yeasts, moulds, algae, viruses and other microorganisms

2. Morphology, structure, reproduction, isolation, and cultivation

3. Principles of taxonomy and classification, Mutants, Control of microorganisms

4. Laboratory experiments in use of microscopy for identification

of microorganisms by morphology and staining technique. Isolation of pure culture

5. Study of growth and optimisation of conditions

6. Preparation of culture media, Sterility test

7. Basic methods in Molecular Biology, including PCR, Blotting techniques,

DNA purification, DNA sequencing etc

PRACTICAL - II

INSTRUMENTAL METHODS OF ANALYSIS / NDDS

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds.

- 2. Estimation of sulphanilamide by colorimetry.
- 3. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy.
- 4. Estimation of quinine sulphate by fluorimetry.
- 5. Study of quenching of fluorescence.
- 6. Determination of sodium by flame photometry.
- 7. Determination of potassium by flame photometry.
- 8. Determination of chlorides and sulphates by nephelo-turbidimetry.
- 9. Separation of sugars by thin layer chromatography.

10. Separation of plant pigments by column chromatography.

SEMESTER I

VALUE ADDED COURSE 1 : SOCIAL AND PREVENTIVE PHARMACY

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes.

Course Objectives

1.To learn about the current issues related to health and pharmaceutical problems within the country and worldwide.

2.To learn about the critical way of thinking based on current healthcare development

3.To develop knowledge on solving problems related to health and pharmaceutical issues.

4.To understand the basic of f prevention and control of disease

5..To develop a piece of knowledge Malnutrition and its prevention.

Course Out Comes

6.After completing unit 1, the students will be able to know about Concept of health and disease ; Social and health education

7.After completing unit 2, the students will be able to know about Sociology and health;Hygiene and health

8.After completing unit 3, the students will be know about Preventive medicine

9. After completing unit 4, the students will be know about National health programs

10. After completing unit 5, the students will be know about National health intervention programme

11.After completing unit 6, the students will be know about Health promotion and education

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.	
Unit-II	Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health. Hygiene and health: personal hygiene and health care; avoidable habits.	
Unit-III	Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse.	
Unit-IV	HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.	
Unit-V	National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program.	
Unit-VI	Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.	
	Total Teaching hours	65

	Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
]	Marks	15	05	05	25

Reference Book:

• Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010,

ISBN: 9789380704104, JAYPEE Publications.

- Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications.
- Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014,
 ISBN: 9789351522331, JAYPEE Publications.

• Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications.

• Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14:

9788190128285, Banarasidas Bhanot Publishers.

- Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad.
- · Sociology for Pharmacist by Kevin Taylor, Sarah Nettleton and Geoffery Harding

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

SEMESTER I

VALUE ADDED COURSE 2: PHARMA MARKETING MANAGEMENTPaper code:Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts needs highly qualified researchers,

chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry.

Course Objectives

1.To learn about the marketing management groom

2.To learn about the role in Sales and Product management.

3.To develop knowledge on understanding of marketing concepts

4. To understand the basic of techniques and their applications in the pharmaceutical industry

5..To develop a piece of knowledge market research.

Course Out Comes

6.After completing unit 1, the students will be able to know about general concepts and scope of marketing

7. After completing unit 2, the students will be able to know about Quantitative and qualitative aspects

8.After completing unit 3, the students will be know about Product decision

9.After completing unit 4, the students will be know about Methods, determinants of promotional mix

10. After completing unit 5, the students will be know about Pharmaceutical marketing channels

11.After completing unit 6, the students will be know about Pricing.

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Definition, general concepts and scope of marketing, distinction between marketing & selling. Marketing environment. Industry and competitive analysis. Analysing consumer buying behaviour and industrial buying behaviour.	
Unit-II	Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patient's choice of physician and retail pharmacist. Analysing the Market; Role of market research.	
Unit-III	Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.	
Unit-IV	Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.	
Unit-V	.Pharmaceutical marketing channels: Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management. Professional sales representative (PSR): Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.	
Unit-VI	Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority). Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Reference Book:

Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi.

• Walker, Boyd and Larreche: Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.

• Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill.

- Arun Kumar and N Meenakshi: Marketing Management, Vikas Publishing, India.
- Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition).
- Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context,

Macmillan India, New Delhi.

- Shanker, Ravi: Service Marketing, Excel Books, New Delhi.
- Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT Excel series) Excel Publications.
- Pharmaceutical marketing in India by Subba Rao Chaganti.

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO - Programme Outcome, CO - Course outcome, S - Strong, M - Medium, L - Low

SEMESTER I

VALUE ADDED COURSE 3 : PHARMACEUTICAL REGULATORY SCIENCE Paper code: Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts e is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc.

Course Objectives

1.To Know about the process of drug discovery and development

2. To learn about the role in the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.

3. To develop knowledge on understanding of approval process and their registration in Indian

and international markets.

4.To understand the concept of Drug Discovery

5.. To develop a piece of knowledge n Investigational New Drug

Course Out Comes

6.After completing unit 1, the students will be able to know about general New Drug Discovery and development

7.After completing unit 2, the students will be able to know about Regulatory Approval Process
 8.After completing unit 3, the students will be know about Regulatory authorities and agencies

9.After completing unit 4, the students will be know about Registration of Indian drug product in overseas market

10.After completing unit 5, the students will be know about Clinical trials

11.After completing unit 6, the students will be know about Regulatory Concepts

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
	Course Contents	
Unit I	Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.	
Unit-II	Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.	
Unit-III	Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications).	12 hours
Unit-IV	Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.	
Unit-V	Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials.	
Unit-VI	Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Reference Book:

Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.

• The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.

Martin, Drugs and the Pharmaceutical Sciences, Vol. 185. Informa Health care Publishers.

- New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
- Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
- FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.

• Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143

	Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
	CO1	S	S	S	М	М	М	М	S	S	S
ĺ	CO2	М	М	М	S	S	М	S	S	М	М
ĺ	CO3	М	М	М	S	S	S	S	М	М	М
ĺ	CO4	S	S	S	М	М	М	S	S	М	S
ĺ	CO5	М	М	М	S	М	S	М	М	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

SEMESTER II

PAPER 1: Research Methodology

Subject: M.sc Environmental Biotechnology

Paper code:

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of Research, Literature survey, Documentation, Research report, presentation, protection of patent and trade marks, Design and copyrights, Industrial Institution Interaction.

Course Objectives

1.To learn about objective of research, literary survey, and also to learn about preparing research proposal for different types of research.

2. To learn about the tools used in research

3. To develop knowledge on paper writing, thesis writing,

4. To understand the basic of protection of patent and trade marks, design and copy rights.

5. To develop a piece of knowledge on industrial - institutional interaction.

Course Out Comes

6.After completing unit 1, the students will be able to know the meaning and purpose and types of Research.

7. After completing unit 2, the students will be able to know about how to take a Literature survey.

8. After completing unit 3, the students will be know about how to prepare proposal for different types of research .

9. After completing unit 4, the students will be know about the the Qualitative and Quantitavive studies .

10. After completing unit 5, the students will be know about the Importance and techniques of Documentation.

11.After completing unit 6, the students will be know about how to write a research paper and also to know about the importance of spell check.

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	.Meaning of Research, Purpose of Research, Types of Research (Educational, Clinical, Experimental, Historical, Descriptive, Basic applied and Patent Oriented Research) –Objective of research-	12 hours
Unit-II	Literature survey – Use of Library, Books, & Journals – Medline – Internet, getting patents and reprints of articles as sources for literature survey	, 12 hours
Unit-III	Selecting a problem and preparing research proposal for different types of research mentioned above.	12 hours
Unit-IV	Methods and tools used in Research •Qualitative studies, Quantitative Studies •Simple data organization, Descriptive data analysis	12 hours
	 Limitations and sources of Error Inquiries in form of Questionnaire, Opinionnaire or by interview Statistical analysis of data including variance, standard deviation, students 't' test and annova, correlation data and its interpretation, computer data 	
Unit-V	analysis Documentation •"How" of Documentation •Techniques of Documentation •Importance of Documentation Uses of computer packages in Documentation	12 hours
Unit - VIII	 Oses of computer packages in Documentation Protection of patents and trade marks, Designs and copyrights The patent system in India – Present status Intellectual property Rights (IPR), Future changes expected in Indian Patents Advantages The Science in Law, Turimetrics (Introduction) What may be patented Who may apply for patent Preparation of patent proposal Registration of patent in foreign countries and vice-versa 	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

ſ	Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
ſ	CO1	S	S	S	Μ	Μ	Μ	Μ	S	S	S
Ī	CO2	Μ	Μ	Μ	S	S	Μ	S	S	Μ	Μ
Ī	CO3	Μ	Μ	Μ	S	S	S	S	Μ	Μ	Μ
Ī	CO4	S	S	S	Μ	Μ	Μ	S	S	Μ	S
Ī	CO5	Μ	Μ	Μ	S	Μ	S	Μ	Μ	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

SEMESTER II

PAPER 2: Pharmaceutical Biotechnology II

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of Animal Cell culture , Plant tissue culture, Omics, physical aspects of the genome, Integrons ad transposons, Regular aspects of biotechnology based products.

Course Objectives

1. To learn about Historical background, Importance, Biology of Animal Cell Culture.

- 2. To learn about the evolution of plat tissue culture and also the use of plant growth regulators.
- 3. To develop knowledge on Proteomics, Genomics and Metabolomics .
- 4. To understand the basic of Physical aspects of the genome.
- 5. To develop a piece of knowledge on Integrns and Transposons.

Course Out Comes

6...After completing unit 1, the students will be able to know the Importance of Animal Cell Culture, Cell Differentiation and Cloning .

7. After completing unit 2, the students will be able to know about the basic sspects of Plant tissue culture and Plant growth regulators and secondary metabolites.

8. After completing unit 3, the students will be know about the methods used in analyzing gene expression and their applications.

9. After completing unit 4, the students will be know about the physical aspects of the genome.

10. After completing unit 5, the students will be know about the basic concept of Integrons and Transposons.

11.After completing unit 6, the students will be know about the Regulatory aspects of biotechnology based products.

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hou
Unit I		12 hours
	Animal Cell Culture: Historical Background, Importance of and progress	
	in Animal Cell Culture, Technology, Biology of Animal Cell; Cellular	
	Interactions, Importance of Serum and Serum Free Media, Culturing and	
	Sub-Culturing of Animal Cells, InVitro Transformation of Animal Cells, Cell	
	Differentiation & Cell Movement, Cloning of Animal Cells, Cell Line	
	Preservation, Cell Line Characterization, Chromosome Spreading and	
	Karyotype Analysis, Mycoplasma: Detection and Control, Monoclonal	
•• •4 ••	Antibody Production, Insect Cell Culture: An Overview	441
Unit-II	Plant cell culture: History and evolution, Basics of aseptic culture, In vitro propagation, use of plant growth regulators in tissue culture, plant	
	regeneration, organogenesis, somatic embryogenesis, protoplast isolation and	
	culture, somaclonal variation, in vitro mutagenesis, in vitro selection,	
	secondary metabolite production and cell transformation techniques	
	(including protoplast fusion, direct DNA uptake and plant/ bacterial co-	
	cultivation), use of in vitro techniques for crop improvement.	
	······································	
Unit-III	Omics: Proteomics, Genomics and Metabolomics: Introduction to the	12 hours
	definitions of various 'omics', introduction to the general field of genomics	
	and proteomics, introduction to some methods used in analyzing gene	
	expression at the mRNA and protein level, basic principles of DNA/Protein	
	microarrays and their applications	
Unit-IV	Physical aspects of the genome. Construction and study of various types	12 hours
		12 110013
	of genome maps and large-scale sequencing. The human genome project and	
	the plant genome program. Structural genomics and gene discovery,	
	isolation, localization and characterization. Developing diagnostic tests for	
	plant, animal and human diseases. Identification of biomarkers. Finding	
	genetic markers for plant breeding purposes. Environmental impacts on gene	
	expression. Protein complex structures and amino acids. Protein shapes as	
	affecting its function. Amino acid sequencing. Cellular proteome changes in	
	response to environmental and neighbouring cells conditions. Cataloguing	
	the proteins produced by different cells. Discovering the function of a	
	protein. Determining three-dimensional structure of proteins. Protein	
	crystallography	
Unit-V		12 hours
Unit- v	integrons and transposons	12 110015
Unit-VI	Regulatory aspects of biotechnology based products	05 hours
ł		

Distribution for	Test (CIA I + CIA	Seminars	Assignment	Total marks					
internals	II + CIA III)								
Marks	15	05	05	25					

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

Mapping with Programme Outcomes

PO –Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

PAPER 3: Advanced Analytical Tools in Biotechnology

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of Diagnostic methods and Genome and Post Genomic Analytical Biotechnology and also the Immunological methods and also the Introduction to Bio informatics.

Course Objectives

- 1. To learn about Molecular Methods and also PCR related Techniques.
- 2. To learn about the Gene purification and sequencing and its applications.
- 3. To develop knowledge on Immunological methods and techniques for measurements.
- 4. To understand the basic introduction to bio informatics.
- 5. .To develop a piece of knowledge about the databases and sequence alignments.

Course Out Comes

6.After completing unit 1, the students will be able to know the Molecular methods, blotting techniques, Sequencing and also the PCR techniques.

7. After completing unit 2, the students will be able to know about the basic of gene sequencing and purification and also the goal and application of genomic and proteomics.

8. After completing unit 3, the students will be know the Immunological Methods and Immuno chemical techniques for separation.

9. After completing unit 4, the students will be know about the biological databases, primer designing, gene finding and protein sequencing analysis.

10..After completing unit 5, the students will be know about the law of absorption fluorimetry

11..After completing unit 6, the students will electrophoresis.

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Diagnostic Methods - Molecular Methods: Isolation and purification of nucleic acid and protein, Electrophoresis and visualization of nucleic acid and protein, Blotting techniques, Sequencing and amplification techniques, PCR and related techniques	12 hours
Unit-II	Genomic and Post-Genomic Analytical Biotechnology: Gene purification and sequencing, Protein sequencing and purification, The goal and applications of genomics and proteomics, Techniques in use for gene and protein analysis, e.g. crystallography, magnetic resonance	
Unit-III	Immunological Methods: Antibody production and labeling, Immuno chemical techniques for in situ analyses (ICC and IHC), Immuno-chemical techniques for measurement (ELISA, etc), Immuno chemical techniques for separation (Immunoprecipitation, etc)	
Unit-IV	Introduction to Bio-informatics: organization of biological data, databases (raw and processed), quering in databases, primer designing, gene finding, motif finding, sequence alignment, protein sequence analysis	12 hours
Unit-V	Principle and law of absorption fluorimetry, colorimetry, spectrophotometry (visible, UV, infrared), Centrifugation, cell fractionation techniques, isolation of sub-cellular organelles and particles.	
Unit-VI	Introduction to electrophoresis. Starch-gel, polyacrylamide gel (native and SDS-PAGE), agarose-gel electrophoresis, pulse field gel electrophoresis, immuno- electrophoresis, isoelectric focusing, Western blotting. Introduction to Biosensors and Nanotechnology and their applications.	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

PAPER 4: Physical Chemistry Concepts in

Pharmaceuticals

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of Importance of chemistry in pharmacy. Important terminologies: Pharmacodynamics, Pharmacokinetics, Pharmacopoeia (IP,BP,USP)

Course Objectives

- 1. To learn about :Colloids, Colloidal System and their pharmaceutical applications
- 2. To learn about the Importance of studying physical properties
- 3. To develop knowledge on concept of viscosity
- 4. To understand the Micromeritics
- 5. .To develop a piece of knowledge about the Neutron activation analysis.

Course Out Comes

- 6.After completing unit 1, the students will be able to know Surface Chemistry
- 7. After completing unit 2, the students will be able to know Physical properties of drug molecule
- 8. After completing unit 3, the students will be know the Rheology of pharmaceutical systems
- 9. After completing unit 4, the students will be know about Chemical Kinetics
- 10..After completing unit 5, the students will be know about the Isotopic Dilution analysis
- 11..After completing unit 6, the students will radio pharmaceuticals

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I		12 hours
	Colloids, Colloidal System and their pharmaceutical applications. Types of solutions and their properties, Solid and Crystalline State-Formation of solids, types of solids, nature of amorphous and crystalline solids, crystal systems, determination of crystal structure, polymorphism	
Unit-II	Importance of studying physical properties.Refractive index- Definition, explanation, formula, importance, determination, specific & molar refraction. Optical activity/rotation- monochromatic & polychromatic light, PPL, optical activity, angle of rotation, specific rotation & its examples, measurement of optical activity & its importance. Dielectric constant & Induced Polarization- Dielectric constant explanation & determination, Importance of Dielectric constant. Induced polarization. Permanent dipole moment- explanation & importance	
Unit-III	Introduction, Definition, Applications, concept of viscosity, Newton's law offlow, Kinematic, Relative, Specific, Reduced & Intrinsic viscosity. Newtonian system, Non- Newtonian system- Plastic flow, Pseudoplastic flow, Dilatent flow. Thixotropy, Brief explanation of Bulges & Spurs, rheopexy, measurement of thixotropy and its applications, Negative thixotropy. Viscosity measurements- selection of viscometer for Newtonian and non Newtonian system, Viscoelasticity & its applications	12 hours
Unit-IV	Rates and order of reactions, pharmaceutical applicationsMicromeritics- Introduction to fundamental and derived properties, methods to determine particle size, shape and surface area, density and bulkiness, flow properties compaction. Interfacial phenomenon: Surface tension and surface free energy.	12 hours
Unit-V	principle and applications, Neutron activation analysis : Principle, advantages and limitations, Scintillation counters :Body scanning.	12 hours
Unit-VI	Properties of various types of radiopharmaceuticals, Radiopharmaceuticals as diagnostics, as therapeutics, for research and sterilization.	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

1) Practical Pharmaceutical Chemistry Vol I &II by Beckett and Stenlake.

2) Physical Pharmacy and Pharmaceutical Sciences by Martins, Patrick J. Sinko, Lippincott. William and Wilkins.

3) Cooper and Gunn's Tutorial Pharmacy ,6th edition by S.J. Carter, CBS Publisher Ltd.

4) Instrumental method of Analysis : Hubert H ., Willard ,7th edition.

5) Physical Chemistry- Bahl and Tuli

6) Text Book of Physical Pharmaceutics, IInd edition, Vallabh Prakashan-.C.V.S. Subramanyam.

7) Medicinal Chemistry (Organic Pharmaceutical Chemistry), G.R Chatwal, Himalaya Publishing house.

8) Radiopharmaceuticals in modern pharmacy and nuclear medicine, Richard J. Kowalsky, Steven W. Falen, Oct.2004, 2nd edn., Amer Pharmacists association.

9) Radiopharmaceuticals-Adrian D. Nunn, Marcel Dekker Publishers.

10) Physical Pharmacy- Physical Chemical principles in the pharmaceutical sciences, Alfred Martins, James Swarbrick, Arthur Cammarata ,3rd edition Indian edition, K.M.Varghese Publishing House.

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
C01	S	S	S	Μ	Μ	Μ	Μ	S	S	S
CO2	Μ	М	М	S	S	Μ	S	S	М	Μ
CO3	Μ	М	М	S	S	S	S	М	М	Μ
CO4	S	S	S	М	Μ	Μ	S	S	М	S
CO5	Μ	Μ	Μ	S	Μ	S	Μ	Μ	S	S

Mapping with Programme Outcomes

PO - Programme Outcome, CO - Course outcome, S - Strong, M - Medium, L - Low

SEMESTER II ELECTIVE PAPER 1 : Organic Chemistry I

Paper code: Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts of Chemical Bonding, Molecular Properties of organic molecules.

Course Objectives

- 1. To learn about the concept of Vander waals, ion-dipole bonds
- 2. To learn about the concept of Electronic effects
- 3. To develop knowledge on Stereochemical Principles
- 4. To understand the concept of Classification of reactions
- 5. .To develop a piece of knowledge about Organic Reaction Mechanisms

Course Out Comes

6.After completing unit 1, the students will be able to know about the Chemical Bonding in Organic Molecules

7. After completing unit 2, the students will be able to know Molecular Properties of organic molecules

8. After completing unit 3, the students will be know the Stereochemistry

9.After completing unit 4, the students will be know about reaction intermediate

10..After completing unit 5, the students will be know about theOrganic Reaction Mechanisms

11..After completing unit 6, the students will Electrophilic Aromatic Substitution

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
	Course Contents	
Unit I	Covalent, Ionic, Hydrogen, Vander waals, ion-dipole bonds with examples	12 hours
Unit-II	Hydrophilicity, Hydrophobicity, acidity, basicity, Electronic effects- (Inductive, resonance, mesomeric), Steric effec	12 hours
Unit-III	Stereochemical Principles – Enantiomeric relationships, diastereomeric Relationships, R and S, E and Z nomenclature, dynamic stereochemistry, prochiral relationships,Stereospecific and stereoslective reactions. Stereochemistry of compounds containing phosphorus, sulphur and nitrogen. Introduction of optical activity in the absence of chiral carbon (biphenyl, allenes, spiranes and helical structures). Conformation of acyclicmolecules and shape of six membered rings	12 hours
Unit-IV		12 hours
Unit-V	Aliphatic Nucleophilic substitution-The SN2, SN1, mixed SN1 and SN2 and SET mechanism. Nucleophilic substitution at an allylic aliphatic trigonal and vinylic carbon. Reactivity effects of structure, attacking nucleophile, leaving group, and reaction. Medium, phase transfer catalyst and ultrasound, ambident nucleophile, Regioselectivity	
Unit-VI	The arenium ion mechanism, orientation and reactivity, energy profile diagram. The ortho/para ratio, ipso attack, orientation in other ring systems. Diazonium coupling, Vilsmeier reaction, Gatterman-Koch reaction.	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

- 1) Modern Synthetic Reaction, by H.O.House, W.A. Benjamin INC 1972.
- 2) Modern methods of Organic Synthesis , by W. Carruthers, Cambridge University Press.
- 3) Organic Synthesis, by Michael B Smith , 2nd edition, London, McGraw Hill 2002.

4) Modern Organic Synthesis An Introduction, George S. Zueifel, Michael H. Nantz, New York.

5) Oxidation & Reduction in Organic Synthesis, Timothy T. Donohoe, OxfordOxford University Press 2000.

6) Sterochemistry – Conformation and mechanism, P.S. Kalsi, New age International(P), Ltd Publishers.

7) J. March (Ed. V) Adv. Organic Chemistry.

8) Stereochemistry of organic compounds by D. Nasipuri.

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	Μ	Μ	Μ	Μ	S	S	S
CO2	М	М	М	S	S	Μ	S	S	М	Μ
CO3	Μ	М	Μ	S	S	S	S	Μ	М	М
CO4	S	S	S	М	Μ	Μ	S	S	М	S
CO5	Μ	М	Μ	S	Μ	S	Μ	Μ	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

ELECTIVE PAPER 2 : Unit Operation in Bioprocesses

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts of Downstream Processing, Cell disruption methods.

Course Objectives

- 1. To learn about the concept of bioprocess designing.
- 2. To learn about the concept of Cell disruption methods
- 3. To develop knowledge on Enrichment operations
- 4. To understand the concept of electrophoretic separations
- 5. .To develop a piece of knowledge about Ultracentrifugation.

Course Out Comes

6.After completing unit 1, the students will be able to know about the Ultracentrifugation

7. After completing unit 2, the students will be able to know Primary separation and recovery processes.

8. After completing unit 3, the students will be know the Enrichment operations

9. After completing unit 4, the students will be know about Product resolution / fractionation

10..After completing unit 5, the students will be know about the Product finishing

11..After completing unit 6, the students will be know about the Process Analytical Technology

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
	Course Contents	
Unit I	Downstream Processing in Biotechnology, Selection of unit operation with due consideration of physical, chemical and biochemical aspect of biomolecules, basic review of bioprocess designing	
Unit-II	Primary separation and recovery processes: Cell disruption methods for intracellular products, removal of insolubles, biomass (and particulate debris) separation techniques, flocculation and sedimentation, centrifugation and filtration methods.	
Unit-III	Enrichment operations: Membrane – based separations (micro and ultrafiltration, precipitation methods, extractive separation, aqueous two-phase extraction, supercritical extraction, insitu product removal, integrated bioprocessing.	12 hours
Unit-IV	Product resolution / fractionation: Adsorptive chromatographic separations processes, electrophoretic separations, hybrid separation technologies (electrochromatography).	12 hours
Unit-V	Product finishing: precipitation/crystallization, mixing, dialysis, distillation and drying. Ultracentrifugation as a separation technique for fractionation of cells and proteins.	12 hours
Unit-VI	Introduction to Process Analytical Technology (PAT) and Quality by Design (QbD). Scale down, monitoring and Validation of bioprocesses.	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
COI	S	S	S	Μ	Μ	Μ	Μ	S	S	S
CO2	M	Μ	Μ	S	S	М	S	S	Μ	М
CO3	M	Μ	Μ	S	S	S	S	Μ	Μ	М
CO4	S	S	S	Μ	Μ	Μ	S	S	Μ	S
COS	M	Μ	Μ	S	Μ	S	Μ	Μ	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

SEMESTER II ELECTIVE PAPER 3: ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Paper code:

Aim: To enable the students to understand the basic concepts of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

Course Objectives

1. To learn about the concept of the latest technology development in biotechnology technique,

tools and their uses in drug and vaccine development.

- 2. To learn about the concept to Identify appropriate sources of enzymes.
- 3. To develop knowledge on Understand and perform genetic engineering techniques in

gene manipulation, rDNA technology and gene amplification.

4. To understand the concept of Understand the overview of pharmacogenomics

5. .To develop a piece of knowledge about the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

Course Out Comes

6.After completing unit 1, the students will be able to know about the impact of genetic engineering in modern society, the students should be endowed with strong theoretical knowledge of this technology.

7. After completing unit 2, the students will be able to know The basics of enzyme technologies used in pharmaceutical industry

8. After completing unit 3, the students will be know the Understand the overview of pharmacogenomics.

9. After completing unit 4, the students will be know about Therapeutic peptides

10..After completing unit 5, the students will be know about the Signal transduction

11..After completing unit 6, the students will Microbial Biotransformation

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours	
Unit I	Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.	12 hours	
Unit-II	Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E. coli and yeast. Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences. Gene library and cDNA Applications of the above technique in the production of, a) Regulatory proteins: Interferon, Interleukins b) Blood products: Erythropoietin c) Vaccines: Hepatitis-B d) Hormones: Insulin		
Unit-III	Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration. • Transgenic animals • Production of useful proteins in transgenic animals and gene therapy. • Human Genome • The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes	12 hours	
Unit-IV	Introduction, cell signalling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases	12 hours	
Unit-V	Oncogenes, Introduction, definition, various oncogenes and their proteins.	12 hours	
Unit-VI	Biotransformation for the synthesis of chiral drugs and steroids. • Microbial Biodegradation • Biodegradation of xenobiotics, chemical and industrial wastes, Production of singlecell protein, • Applications of microbes in environmental monitoring. • Biosensors, Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors		
	Total Teaching hours	65	

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.

2. Immobilization of cells and enzymes: Hosevear Kennadycabral & Bicker staff

3. Principles of Gene Manipulating: RW Old and S. B. Primrose.

4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S Lawence Zipursky, Paul Matsudaira, James Darnell.

5. Modern Biotechnology: S.B Primros.

6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray

7. Current protocols in Molecular Biology, Vol. I & II F.M. Asubel, John Wiley Publishers

8. Current protocols in cellular biology, Vo1.1 & II John Wiley publishers.

9. Principles of human genetics; by Curt Stern, published by W.H. Freeman

	Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
	CO1	S	S	S	Μ	Μ	Μ	Μ	S	S	S
ĺ	CO2	Μ	Μ	Μ	S	S	Μ	S	S	Μ	Μ
	CO3	М	Μ	Μ	S	S	S	S	Μ	Μ	М
ĺ	CO4	S	S	S	Μ	М	Μ	S	S	М	S
	CO5	М	Μ	М	S	М	S	Μ	М	S	S

Mapping with Programme Outcomes

PO - Programme Outcome, CO - Course outcome, S - Strong, M - Medium, L - Low

PRACTICAL -III

PHARMACEUTICAL BIOTECHNOLOGY - I

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer

2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3.Experiments based on HPLC

4. Experiments based on Gas Chromatography

5.Estimation of riboflavin/quinine sulphate by fluorimetry

6.Estimation of sodium/potassium by flame photometry

7. Isolation and Purification of microorganism from the soil

8. Microbial contamination of Water and biochemical parameters.

9.Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.

10. UV- survival curve and Dark repair

PRACTICAL -IV

PHARMACEUTICAL BIOTECHNOLOGY - II

1.Synthesis of organic compounds by adapting different approaches involving (3 experiments)

a) Oxidation b) Reduction/hydrogenation c) Nitration

2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)

3. Assignments on regulatory requirements in API (2 experiments)

4. Comparison of absorption spectra by UV and Wood ward - Fieser rule

5.Interpretation of organic compounds by FT-IR

6.Interpretation of organic compounds by NMR

7.Interpretation of organic compounds by MS

8.Determination of purity by DSC in pharmaceuticals

9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra

10. To carry out the preparation of following organic compounds

OPEN ELECTIVE 1: Biochemical Engineering

Fundamentals

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts of thermodynamics, Reaction yield; Reaction rate.

Course Objectives

- 1. To learn about the concept of Kinetics of microbial growth.
- 2. To learn about the concept of Monitoring and control of bioreactors
- 3. To develop knowledge on Continuous operation of a mixed reactor;
- 4. To understand the concept of types of agitational methods
- 5. .To develop a piece of knowledge about Mechanisms of heat transfer.

Course Out Comes

- 6.After completing unit 1, the students will be able to know about the Homogenous reactions
- 7. After completing unit 2, the students will be able to know about the Microbial growth
- 8. After completing unit 3, the students will be know the Reactor design-I
- 9.After completing unit 4, the students will be know about Reactor design-II
- 10..After completing unit 5, the students will be know about the Agitation
- 11..After completing unit 6, the students will Heat transfer in bioreactors

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Reaction thermodynamics; Reaction yield; Reaction rate; Reaction kinetics; Calculation of reaction rates from experimental data; General reaction kinetics for biological systems; Zero-order kinetics; Michaelis-Menten kinetics; Determining enzyme kinetic constants from batch data	
Unit-II	: Kinetics of microbial growth; substrate utilization and product formation; Structured and unstructured model for growth	12 hours
Unit-III	Bioreactor configurations; Stirred tank; Airlift reactor; Packed bed; Monitoring and control of bioreactors; Ideal reactor operation	12 hours
Unit-IV	Batch operation of a mixed reactor; Total time for batch reaction cycle; Continuous operation of a mixed reactor; Chemostat cascade; Continuous operation of a plug flow reactor	12 hours
Unit-V	Need of agitation in aerobic fermentation; Effect of agitation; How agitation helps aeration; different types of agitational methods; impeller design	
Unit-VI	Mechanisms of heat transfer; heat transfer between fluids; Calculation of heat transfer co-efficients; Heat transfer equipment; Steady state conductance; LMTD calculation	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

1.Bioprocess engineering: Basic concept by Michael L. Shuler, Fikret Karg

2.Bioprocess engineering Principles by Pauline M. Doran

3. Biochemical Engineering Fundamentals by James Edwin Bailey, David F. Ollis

4. Principles of Fermentation Technology by Peter Stanbury, Allan Whitaker, Stephen Hall

5. Biotol series (This series has many books pertaining to all fields of Biotechnology, students have to select the books as per the topic of interest).

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO - Programme Outcome, CO - Course outcome, S - Strong, M - Medium, L - Low

OPEN ELECTIVE 2: Biotechnology in Pharmaceutical

Sciences

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts of drug discovery, Genomics, Cloning and characterization of biopharmaceuticals.

Course Objectives

Paper code:

- 1. To learn about the concept of target based drug design and target discovery
- 2. To learn about the concept of genome sequencing and sequence comparison methods
- 3. To develop knowledge on Isolation and validation of targets,
- 4. To understand the concept of Protein expression systems
- 5. To develop a piece of knowledge about Enzyme purification and assay.

Course Out Comes

6.After completing unit 1, the students will be able to know about the the application of molecular biology and genetic engineering tools in research, therapeutics, industries and forensics.

7. After completing unit 2, the students will be able to know the interpretation of molecular research published in the scientific research literature.

8. After completing unit 3, the students will be know the the genetic machinery of cells, gene transcription, translation, and regulation, along with technical understanding of gene editing tools and its applications.

9. After completing unit 4, the students will be know about e the advances in immunology towards biotechnology, development of hybridoma, vaccines, peptides, lymphokines, antibodies.

10..After completing unit 5, the students will be know about the Various protein purification methods

11..After completing unit 6, the students will Introduction to microbial growth.

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	.Biology in drug discovery; Traditional drug discovery vs. rational drug discovery, rational drug discovery pipeline, concept of target based drug design and target discovery, role of plant biotechnology in edible vaccine development	12 hours
Unit-II	Concept of genome, genes and gene expression, genome sequencing and sequence comparison methods (e.g. BLAST), gene expression comparison methods (microarray). Comparative genomics and expression genomics for target discovery of communicable diseases and lifestyle disease.	
Unit-III	Isolation and validation of targets, PCR, RT-PCR nucleic acid isolation, cloning vectors (some examples), enzymes used in molecular cloning methods (some examples). Cloning and characterization of biopharmaceuticals.	12 hours
Unit-IV	Gene expression in bacteria, yeast, insect and mammalian cells.	12 hours
Unit-V	Various protein purification methods, enzyme based assay for small molecule screening.	12 hours
Unit-VI	Upstream process: Introduction to microbial growth, media formulation, sterilization, inoculum preparation.	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

 $PO-Programme\ Outcome,\ CO-Course\ outcome,\ S-Strong,\ M-Medium,\ L-Low$

OPEN ELECTIVE 3: Analysis, Diagnostics and Cell

based Screening

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts of diagnostic immunoassays, biochemical and cellular assays.

Course Objectives

- 1. To learn about the basic concept of homogeneous immunoassays
- 2. To learn about the basic concept of DNA probe based diagnostics
- 3. To develop knowledge on Biomarkers
- 4. To understand the concept of Requirements and parameters
- 5. .To develop a piece of knowledge about Assays compatible with cell membranes

Course Out Comes

6.After completing unit 1, the students will be able to know about the Principles, methods and applications of immuno-diagnostics

7. After completing unit 2, the students will be able to know Principles, methods and applications of

DNA-based diagnostics

8. After completing unit 3, the students will be know the Diagnostics

9. After completing unit 4, the students will be know about High-throughput screening

10..After completing unit 5, the students will be know about theScreening assays

11..After completing unit 6, the students will Yeast two-hybrid system:

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units		Teaching hours
	Course Contents	
Unit I	: Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous immunoassays, fluorescence, chemiluminescence and bioluminescence enzyme immunoassays, immunoblot, immunoaffinity, immunoprecipitation, biotinylation, immunosensors	
Unit-II	DNA probe based diagnostics, sample preparation, hybridization, separation, detection, PCR-RFLP in paternity and forensic cases SNP detection MALDI and DHPLC	
Unit-III	Biomarkers and NGS in Diagnostics, human retroviral diseases specially AIDS, Role of enzymes in diagnostics	12 hours
Unit-IV	Requirements and parameters, Advantages and disadvantages of biochemical and cellular assays; miniaturization and automation	12 hours
Unit-V	Advantages over in vitro assays. Formats: radioactive, luminescence, fluorescence, etc. Assays compatible with cell membranes: GTPyS, cAMP accumulation	
Unit-VI	Different Y2H systems, their advantages and disadvantages, examples.	05 hours
	Total Teaching hours	65

	Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
N	Marks	15	05	05	25

References

- 1. The immunoassay Handbook by David Wild
- 2. High Throughput Screening: The Discovery of Bioactive Substances by John P. Devlin
- 3. Practical Biochemistry: Principles and Techniques, by K. Wilson and J. Walker
- 4. Experimental Biochemistry, by R. L. Switzer and L. F. Garrity W. H.
- 5. Principles of Biochemistry by Lehinger.
- 6. Biochemistry by L. Stryer Atul Prakashan

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	Μ	Μ	Μ	Μ	S	S	S
CO2	Μ	Μ	Μ	S	S	Μ	S	S	Μ	М
CO3	Μ	Μ	Μ	S	S	S	S	Μ	Μ	М
CO4	S	S	S	Μ	Μ	Μ	S	S	Μ	S
CO5	Μ	Μ	Μ	S	Μ	S	Μ	Μ	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

COMPULSORY PAPER 1: Introduction to Cancer Biology

Paper code:	Subject:M.sc Environmental Biotechnology
Hours/Week: 5Credits: 2	
Aim: To enable the students to understa	and the basic concepts of Carcinogenesis.

Course Objectives

- 1. To learn about the concept of stages of carcinogenesis
- 2. To learn about the concept of role of transcription factors and miRNA
- 3. To develop knowledge on dysregulation in cancer
- 4. To understand the concept of Cancer stem cells
- 5. .To develop a piece of knowledge about chemotherapy,

Course Out Comes

6.After completing unit 1, the students will be able to know about the molecular and cellular process that leads to cancer

7. After completing unit 2, the students will be able to know the recent advances and methods involved in cancer research

8. After completing unit 3, the students will be know the the tools and techniques involved in cancer diagnostics and research

9. After completing unit 4, the students will be know about cancer therapies and the scientific rationale for developing new treatments

10..After completing unit 5, the students will be know about the Preclinical molecular imaging

11..After completing unit 6, the students will chemo prevention

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Define cancer, various types, hallmarks of cancer, stages of carcinogenesis, Tumor microenvironment, importance of extracellular matrix, immunosurvelliance and immunoediting with respect to tumorigenesis	12 hours
Unit-II	Mutations, oncogenes, tumor suppressor genes, mutagens, gene dysregulation, DNA damage and repair, epigenetic alterations, role of transcription factors and miRNA	
Unit-III	Role of receptors (GPCRs, TRKs), cell cycle dysregulation in cancer, altered metabolism, warburg effect.	12 hours
Unit-IV	Cancer stem cells, their role in cancer progression, cancer stem cell markers, extracellular vesicle (exosomes etc.), in-vitro tumor models (2D, 3D, patient-derived models), pre-clinical mouse models.	12 hours
Unit-V	Preclinical molecular imaging, biopsy (tissue and liquid), laboratory investigations, tumor and circulating biomarkers, therapeutic targets, TNM staging, NGS based diagnostics	
Unit-VI	Surgery, radiotherapy, chemotherapy, immunotherapy, hormonal, and combinational therapy, precision medicine, chemoprevention (natural or chemically synthesized compounds), development of resistance, synthetic lethality	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

- 1. The Cell: A Molecular Approach by Geoffrey M. Cooper, Robert E. Hausman
- 2. Molecular Biology of the Cell, by Bruce Albert
- 3. Hallmarks of Cancer: The Next Generation by Douglas Hanahan, Robert A. Weinberg
- 4. Relevant review & research papers.

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

CORE PAPER 1: BIOPROCESS & FERMENTATION TECHNOLOGY

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of Bioprocess Technology. Course Objectives

- 1. To learn about the concept of bioprocess engineering
- 2. To learn about the concept of fermentation processes
- 3. To develop knowledge on Media formulation
- 4. To understand the concept of sugar conversion processes and their downstream processing
- 5. .To develop a piece of knowledge about Fermented foods and beverages

Course Out Comes

6.After completing unit 1, the students will be able to know about Basic principles of Bioprocess Technology

7. After completing unit 2, the students will be able to know the Concepts of basic mode of fermentation processes

8. After completing unit 3, the students will be know the the Upstream and downstream processing9.After completing unit 4, the students will be know about Applications of enzymes in food

processing

10..After completing unit 5, the students will be know about Applications of Microbes in food process operations and production

11..After completing unit 6, the students will Fermenter Design & types

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Introduction to concepts of bioprocess engineering, Overview of bioprocesses with their various components, Isolation, screening and maintenance of industrially important microbes; Strain improvement for increased yield and other desirable characteristics, Microbial growth and death kinetics with respect to fermenters, optimization of bioprocesses, yield coefficient, doubling time, specific growth rate, metabolic and biomass productivities, effect of temperature, pH and salt concentration on product formation.	
Unit-II	Bioreactor designs; Types of fermenters; Concepts of basic modes of fermentation - Batch, fed batch and continuous; Solid substrate, surface and submerged fermentation; Fermentation media; Design and types of culture/production vessels- Batch, Fed batch, CSTBR, airlift, packed bed and bubble column fermentor; Impeller, Baffles, Sparger.	
Unit-III	Media formulation; Inocula development and Sterilization; Aeration and agitation in bioprocess; Measurement and control of bioprocess parameters; Scale up and scale down process. Bioseparation techniques; Cell disruption methods; Liquid-liquid extraction; Purification by chromatographic techniques; Reverse osmosis and ultrafiltration, drying, crystallization, storage and packaging; Treatment of effluent and its disposal	12 hours
Unit-IV	Mechanism of enzyme function and reactions in process techniques; Enzymic bioconversions e.g. starch and sugar conversion processes and their downstream processing; baking by amylases, deoxygenation and desugaring by glucose oxidase, beer mashing and chill proofing; cheese making by proteases	12 hours
Unit-V	Fermented foods and beverages; cheese and bread production, food ingredients and additives prepared by fermentation and their purification; fermentation as a method of preparing and preserving foods; Microbes and their use in pickling, producing colours and flavours, alcoholic beverages and other products; Process wastes-whey, molasses, starch substrates and other food wastes for bioconversion to useful products, probiotics, prebiotics and symbiotics.	
Unit-VI	Fermenter Design, Design of a typical aerobic fermenter, A study of the parameters to be considered in designing a typical fermentor, Examples of fermenters, i. Mechanical – Typical fermentor, Waldoff fermenter, ii. Hydrodynamic- deep-jet fermenter, iii. Pneumatic - air-lift fermenter, bubble- cap fermenter. Modes of fermentation operation, Aerobic & Anaerobic, Surface & Submerged, Batch & Continuous	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

1).Casida LE. (1991). Industrial Microbiology. 1st edition. Wiley Eastern Limited.
Crueger W and Crueger A. (2000).

2)Biotechnology: A textbook of Industrial Microbiology. 2nd edition, Panima Publishing Co. New Delhi. □ Patel AH. (1996).

3)Industrial Microbiology. 1st edition, Macmillan India Limited. 🗆 Jackson AT.,

4)Bioprocess Engineering in Biotechnology, Prentice Hall, Engelwood Cliffs, 1991.

Γ	Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
	CO1	S	S	S	М	М	М	М	S	S	S
	CO2	М	М	М	S	S	М	S	S	М	М
	CO3	М	М	М	S	S	S	S	М	М	М
	CO4	S	S	S	М	М	М	S	S	М	S
	CO5	М	М	М	S	М	S	М	М	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

CORE PAPER 2: PHARMACEUTICAL BIOTECHNOLOGY AND DRUG DESIGNING

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of Drug discovery methods. Course Objectives

- 1. To learn about the concept of metabolic enzymes involved in nucleic acid synthesi
- 2. To learn about the concept of Drug Discovery Process
- 3. To develop knowledge on , Validation techniques of Pharmaceutical targets
- 4. To understand the concept of drug delivery and drug targeting
- 5. .To develop a piece of knowledge about Formulation of Biotechnological Products

Course Out Comes

6.After completing unit 1, the students will be able to know about metabolic enzymes involved in nucleic acid synthesis

7. After completing unit 2, the students will be able to know the Drug discovery methods

8. After completing unit 3, the students will be know the the Concepts of Bio availability

9. After completing unit 4, the students will be know about : Pharmacology of drugs

10..After completing unit 5, the students will be know about Formulations

11..After completing unit 6, the students will be known about Regulation of Pharmaceutical Biotechnological Products.

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Introduction and History, DNA, RNA, post-translational processing, metabolic enzymes involved in nucleic acid synthesis, G-protein coupled receptors (monomeric transmembrane proteins), small molecule receptors, ligand-gated ion channels (oligomeric transmembrane proteins), transporters (multi-transmembrane proteins).	12 hours
Unit-II	Meaning of drugs, Drug Discovery Process, biological activity directed and other types of screening, natural products, combinatorial chemistry; General overview of validation techniques, Methods of Drug Discovery and development, QSAR and SAR	
Unit-III	Concepts of Bio availability, Process of drug absorption, Pharmacokinetic processes, Timing for optimal therapy, Drug delivery considerations for the new biotherapeutics.	12 hours
Unit-IV	 Physicochemical Properties in Relation to Biological Action, Effects of route of administration, Drug Targets, Validation techniques of Pharmaceutical targets, Pharmacokinetics and pharmaco dynamics of drugs, Drug Toxicity. Basic terminologies in drug delivery and drug targeting, Doses forms, Various routes of administration of drugs (just introduction), Strategies for enhanced therapeutic efficacies (Basic principles) DNA vaccines, Vaccines & Monoclonal antibody based pharmaceuticals, Antibiotics, Characterization and Bio analytical aspects of Recombinant proteins as pharmaceutical drugs. 	12 hours
Unit-V	Formulation of Biotechnological Products, Drug Delivery, Examples of some Biotechnological products in clinical development.	12 hours
Unit-VI	Role of FDA, ICH Guidelines, The Regulation of Pharmaceutical Biotechnological Products and Ethical Issues.	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

1. Drug Delivery and Targeting, A.M. Hillery, A.W. Lloyd and J. Swarbrick, Harwood Academic Publisher

2. Pharmaceutical Dosage Forms and Drug Delivery Systems, H.C. Ansel, L.V. allen and N.G.

4.Introduction to Biophysical Methods for Protein and Nucleic Acid Research, J.A. Glasel and M.P. Deutscher, Academic Press.

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

CORE PAPER 3: Chemistry of Drugs

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Aim: To enable the students to understand the basic concepts of Introduction to Pharmaceuticals.

Course Objectives

- 1. To learn about the concept of Nomenclature of Pharmaceuticals
- 2. To learn about the concept of Sex hormones and related compounds
- 3. To develop knowledge on : Fat soluble vitamins
- 4. To understand the concept of Cholinergic agents
- 5. .To develop a piece of knowledge about Adrenergic and cholinergic drugs

Course Out Comes

6.After completing unit 1, the students will be able to know about Introduction to Pharmaceuticals

7. After completing unit 2, the students will be able to know the biosynthesis of naturally occurring compounds

8. After completing unit 3, the students will be know the Sex hormones and related compounds

9. After completing unit 4, the students will be know about Vitamins

10..After completing unit 5, the students will be know about Adrenergic and cholinergic drugs

11..After completing unit 6, the students will be known about Cholinergic agents

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours 12 hours	
Unit I	Introduction to Pharmaceuticals, Historical development, Classification drugs, Nomenclature of Pharmaceuticals & Drug metabolism reactions.		
Unit-II	Structure, stereochemistry, nomenclature, mode of action, specific clinical applications and structure activity relationships, biosynthesis of naturally occurring compounds and synthesis of prototypical drugs in each category. (Chemical & Pharmacological) for the following classes of drugs	,	
Unit-III) Hormones: Sex hormones and related compounds (Estrogens, Androgens, Progestational agents, Anabolic steroids, Contraceptives), Adrenal cortex hormones, Thyroid hormones and antithyroid drugs, pancreatic hormones, Hypothalamus hormones	12 hours	
Unit-IV	Vitamins: Fat soluble vitamins (A,D,E and K), water soluble vitamins (Folic acid, B12 and C).	12 hours	
Unit-V	Adrenergic and cholinergic drugs (Agonist & antagonists):	12 hours	
Unit-VI	Cholinergic agents: Autonomic blocking and related drugs. Antispasmodic and antiulcer drugs. Antiparkinsonism drugs.	05 hours	
	Total Teaching hours	65	

Distribution for internals			Assignment	Total marks	
Marks	15	05	05	25	

References

Wilson and Gisvolds Textbook of Organic Medicinal and Pharmaceuticals Chemistry, 8th edition, edited by R.F. Doerge, J.B. Lippincott Company, Philadelphia, 1982.

3. Pharmaceutical Chemicals in Perspective, B.G. Reuben and H.A. Wittcoff, John Wiley & Sons, New York, 1989.

4. W.C. Foye, Principles of Medicinal Chemistry, Lea & Febiger, Philadelphia, U.S.A.

4. H. Singh and V. K. Kapoor, Medicinal and Pharmaceutical Chemistry, Vallabh Prakashan, New Delhi 2005 (Latest edition)

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

CORE PAPER 4: CHEMISTRY OF DRUGS -II

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Paper code:

Aim: To enable the students to understand the basic concepts Structure, stereochemistry (wherever involved), nomenclature, mode of action, specific clinical applications and structure activity relationships, and synthesis of prototypical drugs.

Course Objectives

- 1. To learn about the concept of unclassified antibiotics.
- 2. To learn about the concept of . Antimycobacterials
- 3. To develop knowledge on , Anthelmintics
- 4. To understand the concept of Antiamoebic and antiprotozoal drugs
- 5. .To develop a piece of knowledge about Antiviral agents

Course Out Comes

6.After completing unit 1, the students will be able to know about unclassified antibiotics.

- 7. After completing unit 2, the students will be able to know the . Antimycobacterials
- 8. After completing unit 3, the students will be know the the Anthelmintics
- 9.After completing unit 4, the students will be know about Antiamoebic and antiprotozoal drugs
- 10..After completing unit 5, the students will be know about Antiviral agents

11..After completing unit 6, the students will be known about Antineoplastic agents

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Antibacterials: Penicillines, Cephalosporins, Tetracyclines, Aminoglycosides, Chloramphenicol, Macrolides, Lincomycins, Polypeptide antibiotics, Polyene antibiotics. Sulfonamides and Sulfones, fluoroquinolines, Trimethoprim and other unclassified antibiotics.	
Unit-II	Antimycobacterials: Sulfanilamides, p-Aminosalicyclic acid derivatives, Thioamides, Thiourea derivatives, Thiosemicarbonazones, Isoniazid, Kanamycin sulfate, Capreomycin, Rifampin, Pyrazinamide, Anthionamide, Clofazimine, Cyclosporin, Dapsone, Sulfazem. & Antileprotic agents.	
Unit-III	Anthelmintics: Introduction. Tetrachloroethylene, Piperazines, Gentian violet, Pyrantel pamoate, Thiabendazole, Mabendazole, baphenium hydroxynaphthoate, Dichlophene, Niclosamide, levamisole hydrochloride, Tetramisole, Niridazole, Biothional, Antimonypotassium tartarate, Stibiophen, Sodium Stibiocaptate.	12 hours
Unit-IV	Antiamoebic and antiprotozoal drugs: Emetine hydrochloride, 8- Hydroxyquinoline, Iodochlorohydroxyquinol, Metronidazole, Diloxanide furoate, Bilamical hydrochloride, Hydroxystilbamidine isothinate, Pentamidine isothionate, Nifurtimox, Suramin sodium, Carbarsone, Glycobiarsol, Melarsoprol, Sodium stibogluconate, Dimercaprool, Diethycarbamazine citrate, Centarsone, Acetarsone, Antimony potassium tartarate, Bismuth sodium thioglycollate, Sulphonamide, Stibiophen, Bismuth sodium thioglycollamate, Furazolidone.	12 hours
Unit-V	. Antiviral agents: Introduction, Screening methodology, Admantane derivatives (Amantadine, Rimantadine), Idozuridine, Trifluridine, Vidarabine, Ribavarain, Acycloguanosine, Inospiplex, Methisazone, Zidovudine, Acyclovir, Ganciclovir, Foscarnet, Human interferon.	
Unit-VI	Antineoplastic agents: Alkylating agents (Nitrogen mustards, Aziridines, Sulfonic acid Esters, Epoxides, Nitrosoureas, Triazenes, Phosphamides, Mitomycin, comparative activity of alkylating agents). Antimetaboilities: Antifolates (Methotrexate), Mercaptopurine, Thioguanine, fluorouracil, Floxuridine, Cytarabine, Azathioprine, antitumor, antibiotics, Dactinomycin, Daunorubricin, Aclacinomycin, Mithramycin, Bleomycin, Miscellaneous compounds: Cisplatin, Taxol, Gunazole, Pipobromin, Antitumor alkaloids: Vincristine, vinblastin. Hormones agonist and antgonists: Steroids, Tamoxifen, Mitotane, Dromastanolone propionate, Testalactone, Megastrol acetate Immunotherapy.	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

Strategies of Organic Drug Synthesis and Design, D. Lendnicer, John Wiley and Sons, New York. 1998

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

ELECTIVE PAPER 1: DRUG DESIGN AND DRUG DEVELOPMENT

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts of Drug Design & Drug Development

Course Objectives

- 1. To learn about the concept of Quantum Mechanics
- 2. To learn about the concept of QSAR Analysis
- 3. To develop knowledge on Molecular interactions and interactive graphics
- 4. To understand the concept of Single and two compartment pharmacokinetics
- 5. .To develop a piece of knowledge about Peptidomimetics

Course Out Comes

6.After completing unit 1, the students will be able to know about Introduction to Drug Design & Drug Development

7. After completing unit 2, the students will be able to know the Drug Receptor Interactions

8. After completing unit 3, the students will be know the Computer Aided Drug Designing:

9. After completing unit 4, the students will be know about Pharmacokinetics in Drug designing

10..After completing unit 5, the students will be know about Peptidomimetics

11..After completing unit 6, the students will be known about Prodrug Approach

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Definition, History (Chronological Evolution), Drug design approaches, Lead optimization, de Novo drug design. Quantum Mechanics: Introduction to quantum mechanics, postulates of quantum mechanics, Schrodinger equation, Perturbation theories of drug action, Pullman's dispositive bond theory, Role of charge transfer process in drug action, conformational aspects & molecular orbital calculations, molecular orbital approach to drug design with examples.	
Unit-II	Historical background, Receptor theories, Forces involved in drug receptor interactions; covalent & non-covalent interactions; Agonist & Antagonists. QSAR Analysis: Parameters & Biological data for QSAR, Design of Test series in QSAR: Craig plot, Topliss operational scheme, cluster analysis. Quantitative models: Hansch (Extrathermodynamic) , Free Wilson (Additivity model), Mixed approach. Statistical method for QSAR: Regression analysis, multiple regression, stepwise multiple regression, Partial least square analysis. Validation of QSAR models.	
Unit-III		12 hours
Unit-IV		12 hours

Peptidomimetics research, Rational design of Peptidomimetics, nonpeptide, Ligands for peptide receptors, Applications of oligonucleotides in antiviral and antitumoral chemotherapy. Antisense nucleotides designing. Carbohydrate based Therapeutics.					
Basic concept, Common promoities. Reversal of prodrugschemical and enzymatic . Application of prodrug approach to alter taste and odour, reduction of pain at injection site, reduction of gastrointestinal irritability. Alteration of drug solubility, increasing chemical stability. Prevention of presystematic metabolism. Prolongation of drug action, Site spectic drug delivery. Reduction in drug toxicity					
Total Teaching hours					

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

1. The Organic Chemistry of Drug Design and Drug Action. by R.B. Silverman, Academic Press,1992.

2. Drug Designs- A series of monographs in medicinal chemistry edited by A.J. Ariens. Ist edition.

Vol. I, II, V, VIII & IX (only relevant chapters).

3. Comprehensive medicinal chemistry. Peragmon Press. 1990, Vol.4.

4. Burger's Medicinal Chemistry & Drug Discovery . Fifth edition vol-.I, Willey Interscience.

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO - Programme Outcome, CO - Course outcome, S - Strong, M - Medium, L - Low

ELECTIVE PAPER 2: Basics of Pharmaceutical Chemistry

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts Origin, development and scope of chemical sciences, pharmaceutical sciences.

Course Objectives

- 1. To learn about the concept of Pharmacy, pharmacology, pharmacophore, pharmacodynamics
- 2. To learn about the concept of hydrocolloids
- 3. To develop knowledge on , drug formulations
- 4. To understand the concept of drug molecules
- 5. .To develop a piece of knowledge aboutorganoleptic additives.

Course Out Comes

6.After completing unit 1, the students will be able to know about Drugs & Pharmaceuticals

7. After completing unit 2, the students will be able to know the Formulations, Properties & their influence

8. After completing unit 3, the students will be know the the additives in formulation of different dosage forms

9.After completing unit 4, the students will be know about Physical, chemical and biological properties of drug molecules

10..After completing unit 5, the students will be know about Impurities & sources of impurities in drug formulations

11..After completing unit 6, the students will be known about Development of Pharmaceuticals

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Origin, development and scope of chemical sciences, pharmaceutical sciences, introduction to the fundamentals of pharmaceutical sciences,Drug and disease (definition).Historical evolution. Sources-plant, Animal and synthetic Biotechnology and human gene therapy. Terminology: Pharmacy, pharmacology, pharmacophore, pharmacodynamics, Pharmacokinetic-(ADME, Receptors- brief treatment), Metabolites and Anti-metabolites. Nomenclature: Chemical name, Generic name, and Trade names with examples. Classification: Classification based on structures and therapeutic activity with one example each	
Unit-II		12 hours
Unit-III	classification and uses of following additives in formulation of different dosage forms: preservatives, antioxidants, surfactants, hydrocolloids, emulsifying agents, suspending agents, diluents, binders, lubricants, and organoleptic additives. Physical, chemical and biological properties of drug molecules and their influence on drug formulation.	12 hours
Unit-IV	Physical, chemical and biological properties of drug molecules and their influence on drug formulation.	12 hours
Unit-V	Purity-Broad based highest attaninable standard, Biological response VS. Chemical purity and Official standard VIS-VIS manufacturing standards. Specific tests for identifying impuritiesegs. Presence of salicylic acid in Aspirin, 4- aminophenol in Paracetamol, (+)-2-amino-Butan-1- ol in Ethambutol Hydrochloride , Digitonin in Digitoxin etc. Limit tests: Introduction, specificity, sensitivity and Personal errors. Types of limit tests for quantitative determinartion- Limit for insoluble matter, limits for soluble matter, limits for moisture, volatile matter and residual solvents. Limit tests for Acid radical impurities: For Chlorides, Sulphates, Arsenate, arbonate, Cyanide, Nitrate , Oxalate and Phosphate.	

Unit-VI	Introduction to Pharmacopoeias - IP, BP, USP& International	05 hours				
	Pharmacopoeia, National Formularies and Extra Pharmacopoeia. Typical					
	parts of a monograph of Indian pharmacopoeia with examples, quality					
	control and quality assurance, introduction to GLP, GMP, Laboratory					
	Accreditation, quality estimation of aspirin, acetaminophen, isoniazid,					
	ascorbic acid, codeine phosphate, Chloride in Ringers lactate, ethambutol					
	Total Teaching hours	65				

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

- 1. Pharmaceutical Drug analysis by Ashtoshkar
- 2. Pharmaceutical Chemistry by Chatwal.
- 3.Drugs by David Subramanyam.
- 4.British Pharmacopoeia vol I,II
- 5.Indian Pharmacopoeia vol I,II
- 6.Bentley's Text book of pharmaceutics by Rowlins
- 7. The science and practice of pharmacy by Remington
- 8. Introduction to pharmaceuticals by Mittal

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO - Programme Outcome, CO - Course outcome, S - Strong, M - Medium, L - Low

ELECTIVE PAPER 3: MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts to impart knowledge on the area of advances in novel drug delivery systems.

Course Objectives

- 1. To learn about the concept involved in drug targeting
- 2. To learn about the concept of Micro Spheres
- 3. To develop knowledge on , Pulmonary Drug Delivery System
- 4. To understand the concept of therapeutic delivery system
- 5. .To develop a piece of knowledge about Pharmacokinetics

Course Out Comes

6.After completing unit 1, the students will be able to know about Targeted Drug Delivery Systems

7. After completing unit 2, the students will be able to know the Targeting Methods:

8. After completing unit 3, the students will be know the Micro Capsules / Micro Spheres

9. After completing unit 4, the students will be know about Pulmonary Drug Delivery Systems

10..After completing unit 5, the students will be know about Nucleic acid based therapeutic delivery system

11..After completing unit 6, the students will be known about Biodistribution and Pharmacokinetics.

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units		Teaching hours
	Course Contents	
Unit I	Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 hours
Unit-II	Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation	12 hours
Unit-III	Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes	12 hours
Unit-IV	Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 hours
Unit-V	Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems.	
Unit-VI	knowledge of therapeutic antisense molecules and aptamers as drugs of future.	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2.S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Ballabh Prakashan,

New Delhi, First edition 2002.

3.N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition

1997 (reprint in 2001

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

OPEN ELECTIVE 1 : Separation Techniques

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts of separation techniques, chromatographic techniques.

Course Objectives

- 1. To learn about the concept of separation techniques
- 2. To learn about the concept of drug discovery
- 3. To develop knowledge on , bonded phase chromatography
- 4. To understand the concept of Hyphenated Techniques
- 5. .To develop a piece of knowledge about Biochromatography

Course Out Comes

6.After completing unit 1, the students will be able to know about Separation Techniques

7. After completing unit 2, the students will be able to know the principles, classification of chromatographic techniques

8. After completing unit 3, the students will be know the Column Chromatography and Short Column Chromatography

9.After completing unit 4, the students will be know about Flash Chromatography and Vacuum Liquid Chromatography

10..After completing unit 5, the students will be know about Biochromatography

11..After completing unit 6, the students will be known about Hyphenated Techniques

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Matching Table (Put Yes / No in the appropriate box)

Units		Teaching hours
	Course Contents	
Unit I	Need for learning separation techniques, separation techniques in natural product research and drug discovery, extraction techniques.	12 hours
Unit-II	General principles, classification of chromatographic techniques, normal and reverse phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.	12 hours
Unit-III	Column packing, sample loading, column development, detection.	12 hours
Unit-IV	Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.	12 hours
Unit-V	Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.	12 hours
Unit-VI	Introduction to GC-MS and LC-MS techniques and their applications in natural products.	05 hours
	Total Teaching hours	65

Internal Assessment Methods: (25 marks)

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

- 1. Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
- 2. Methods in Biotechnology, Natural Product Isolation by Richard Canell
- 3. Various Reviews and Research Papers

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

OPEN ELECTIVE 2 : Biostatistics

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts of Concepts of hypothesis testing and types of error.

Course Objectives

- 1. To learn about the concept of Measures of central tendencies and dispersion
- 2. To learn about the concept of Common probability distributions and probability distributions
- 3. To develop knowledge on , Simple random
- 4. To understand the concept of Hypothesis testing
- 5. .To develop a piece of knowledge about Post- hoc procedures

Course Out Comes

6.After completing unit 1, the students will be able to know about Statistics

7. After completing unit 2, the students will be able to know the Probability

8. After completing unit 3, the students will be know the Sampling

9. After completing unit 4, the students will be know about Estimation and Hypothesis testing

10..After completing unit 5, the students will be know about Experimental design and analysis of variance

11..After completing unit 6, the students will be known about Correlation and regression

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Introduction, its role and uses. Collection; Organization; Graphics and pictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation.	
Unit-II	Basic concepts; Common probability distributions and probability distributions related to normal distribution	12 hours
Unit-III	: Simple random and other sampling procedures. Distribution of sample mean and proportion.	12 hours
Unit-IV	Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student- t and Chi square tests. Sample size and power.	12 hours
Unit-V	Completely randomized, randomized blocks. Latin square and factorial designs. Post- hoc procedures	12 hours
Unit-VI	Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

- 1. Fundamentals of Biostatistics by Bernard Rosner
- 2. Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon
- 3. Statistical Misconceptions by Huck

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

OPEN ELECTIVE 3: Immunology and Immunotechnology

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 2

Aim: To enable the students to understand the basic concepts Cells and organs of the immune system.

Course Objectives

1. To learn about the concept of Antigen-antibody interactions

2. To learn about the concept of : T cell subsets and surface markers

- 3. To develop knowledge on , synthetic peptides and immune response
- 4. To understand the concept of Lymphoidcells
- 5. To develop a piece of knowledge about structure and function of MHC.

Course Out Comes

6.After completing unit 1, the students will be able to know about Immunity

7. After completing unit 2, the students will be able to know the Cells and organs of the immune system

8. After completing unit 3, the students will be know the Humoral immunity

9. After completing unit 4, the students will be know about Cell mediated immunity

10..After completing unit 5, the students will be know about Natural immunity

11..After completing unit 6, the students will be known about Naturalkiller cells

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Innate and adaptive, immune response memory, specificity and recognition of self and non-self, immunogenicity, antigenicity, physiology of immune response, epitope analysis, synthetic peptides and immune response, immunity to virus, bacteria, fungi.	
Unit-II	Lymphoidcells, T-cells, B-cells, monocytes, phagocytes, mast cells and basophils, primary and secondary lymphoid organs, interplay between cells.	12 hours
Unit-III	Antigen-antibody interactions, affinity, avidity, immunoglobulins, molecular mechanism of generation of antibody diversity, molecular biology of IgG.	12 hours
Unit-IV	T cell subsets and surface markers, T cell-dependent and independent markers, structure and function of MHC, association of MHC with disease susceptibility, structure of T cell antigen receptor.	12 hours
Unit-V	Inflammation, stimuli, chemotaxis, arachidonic acid metabolite and cytokines, vascular modifications, healing and fibrosis	12 hours
Unit-VI	Functional definition, mechanism of lysis, recognition structures, phosphorylation	05 hours
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

References

1. Cellular and Molecular Immunology by Abdul K. Abbas, Andrew H. Lichtman and Shiv Pillai 1.

2. Kuby Immunology by Thomas J. Kindt, Barbara A. Osborne, and Richard A. Goldsby

Mapping with Programme Outcomes

(Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
C	201	S	S	S	М	М	М	М	S	S	S
C	CO2	М	М	М	S	S	М	S	S	М	М
C	CO3	М	М	М	S	S	S	S	М	М	М
C	CO4	S	S	S	М	М	М	S	S	М	S
C	CO5	М	М	М	S	М	S	М	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

PRACTICALS-V

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL

- 1. Protein identification
- 2. Protein characterization
- 3. Protein biochemistry
- 4. Recombinant DNA Technology
- 5. Protein expression
- 6. Protein formulations
- 7. Database searching
- 8. Sequence analysis methods
- 9. Protein structure prediction
- 10. Gene annotation methods

PRACTICALS- VI

- 11.Phylogenetic analysis
- 12. Protein, DNA binding studies
- 13. Preparation of DNA for PCR applications Isolation, Purity and Quantification
- 14. Introduction to PCR working of PCR, Programming.
- 15. Introduction to RT-PCR working, programming.
- 16. Primer design using software.
- 17. Gene DNA amplification by random / specific primers.
- 18. Southern Hybridization
- 19. Western Blotting
- 20. Gene transformation

SEMESTER IV

CORE PAPER 1 : MOLECULAR MODELLING AND DRUG DESIGNING

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 4

Paper code:

Aim: To enable the students to understand the basic concepts of molecular modeling. Course Objectives

- 1. To learn about the concept of quantum mechanics
- 2. To learn about the concept of Bond stretching
- 3. To develop knowledge on , Molecular Dynamics
- 4. To understand the concept of Homology
- 5. .To develop a piece of knowledge about drug action

Course Out Comes

6.After completing unit 1, the students will be able to know about Quantum mechanics & concepts in molecular modeling

7. After completing unit 2, the students will be able to know the : Molecular mechanics and energy minimization

8. After completing unit 3, the students will be know the Molecular Dynamics and Monte Carlo simulation

9. After completing unit 4, the students will be know about Homology modeling

10..After completing unit 5, the students will be know about Drug design

11..After completing unit 6, the students will be known about Protein Structure Prediction

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Introduction – coordinate systems – potential energy surfaces – introduction to quantum mechanics – postulates – Schrodinger wave equation – hydrogen molecule – Born-Oppenheimer approximation, introduction to computer hardware and software	
Unit-II	Empirical force field models – Bond stretching – angle bending – torsional term – nonbonding interactions – thermodynamics properties using a forcefield – derived and non derived energy minimization method – simplex – sequential univariate method – steepest descent method – conjugate gradient method- Newton-Rapson method	
Unit-III	Introduction – Using single Model – time steps – Multiple steps – Setting up MD – energy conservation in MD Simulation Examples – Monte Carlo – Random number generation – Difference in MD & MC.	12 hours
Unit-IV	Comparative modeling of proteins – comparison of 3D structure – Homology – steps in homology modeling – tools – databases – side chain modeling – loop modeling.	12 hours
Unit-V	General approach to discovery of new drugs - lead discovery – lead modification – physiochemical principles of drug action – drug stereo chemistry –drug action - 3D database search – computer aided drug design – docking - molecular modeling in drug design – structure based drug design – pharmacophores - QSAR.	
Unit-VI	Protein Structure Prediction Introduction, Protein Stability and Folding, Application of Hydrophobicity, Superposition of Structures, DALI methods, Evolution of Protein Structures, CASP, Secondary Structure Prediction, Homology Modelling, Fold Recognition, ROSETTA, LINUS.	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

TEXT BOOKS:

1. A. R.Leach - Molecular Modeling Principles and Application, 2nd edition, Longman Publications, 1996.

2. D. Baxivanis and Foulette - Bioinformatics: A Practical Guide to the Analysis of Genes and

Proteins, Wiely Indian Edition, 2001.

REFERENCE BOOK:

1. T K Attwood, D J parry-Smith, Introduction to Bioinformatics, Pearson Education, 1st Edition,

11th Reprint 2005

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

Mapping with Programme Outcomes

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

ELECTIVE PAPER 1:RESEARCH METHODOLOGY, IPR & BIOETHICS

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 3

Aim: To enable the students to understand the basic concepts to provide fundamental theoretical knowledge about Research Methodology, IPR & Bioethics.

Course Objectives

- 1. To learn about the concept involved in Significance of Research
- 2. To learn about the concept of experimental designs
- 3. To develop knowledge on , Qualitative research
- 4. To understand the concept of r intellectual property right
- 5. .To develop a piece of knowledge about bioethics

Course Out Comes

- 6.After completing unit 1, the students will be able to know about Basics of research
- 7. After completing unit 2, the students will be able to know the Research design
- 8. After completing unit 3, the students will be know the Methods of data collection
- 9.After completing unit 4, the students will be know about Qualitative and Quantitative Research
- 10..After completing unit 5, the students will be know about IPR
- 11..After completing unit 6, the students will be known about Bioethics

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Objectives- Types- Significance of Research- Steps in research process Criteria for good research. Defining and formulating a research problem- Literature survey- Development of working hypothesis	
Unit-II	Definition and related concepts, Basic principles of experimental designs- Informal and formal experimental designs; Sampling design: Steps in sample design, Non-probability sampling and Probability sampling -random sampling; Measurement and scaling techniques	
Unit-III	Methods of data collection - Execution of project -Processing and analysis of data Hypothesis testing - Interpretation and report writing- Steps and layout of research reportTypes of report, review paper writing and presentation.	12 hours
Unit-IV	Qualitative research – Quantitative research – Concept of measurement, causality, generalization, replication.Merging the two approaches.	12 hours
Unit-V	Introduction and the need for intellectual property right (IPR) - Kinds of Intellectual Property Rights: Patent, Copyright, Trade Mark, Design, Geographical Indication, Plant Varieties and Layout Design – Genetic Resources and Traditional Knowledge – Trade Secret	
Unit-VI	Introduction to bioethics, ethical issues in preclinical (animal) studies, & clinical studiesEthical principles, Ethical guidelines-ICMR, Institutional Ethics - Institutional Ethics committees, Institutional review board, SOPs, ethical issues based on methodology of clinical research. The ethics of clinical research in developing countries	
	Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	Μ	Μ	Μ	S	М	S	М	М	S	S

PO – Programme Outcome, CO – Course outcome, S – Strong, M – Medium, L – Low

ELECTIVE PAPER 2:BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 3

Aim: To enable the students to understand the basic concepts to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry

Course Objectives

- 1. To learn about the concept involved in Use of computers in developing a new drug
- 2. To learn about the concept of Biological concepts for bioinformatics
- 3. To develop knowledge on , Proteins and their diversity
- 4. To understand the concept of Various gene finding methods
- 5. .To develop a piece of knowledge about Searching the biological databases

Course Out Comes

6.After completing unit 1, the students will be able to know about Develop an understanding of the basic theory of these computational tools

7. After completing unit 2, the students will be able to know the Develop required database extraction, integration, coding for computational tools and methods necessary for all Omics

8. After completing unit 3, the students will be know the Create hypothesis for investigating specific contemporary biological questions, provide help to experiment with or develop appropriate tools, Searching the biological databases and understanding various methods of drug designing
9. After completing unit 4, the students will be know about Protein structure prediction
10.. After completing unit 5, the students will be know about Diversity of Genomes

11..After completing unit 6, the students will be known about Target searching and Drug Designing

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Introduction to Bioinformatics Definition and History of Bioinformatics Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics, Biological DatabaseProtein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.	f 1
Unit-II	Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.	5
Unit-III	Protein informatics Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R & S fit of conformers, assigning secondary structures; Sequence alignmentmethods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.	12 hours
Unit-IV	Protein structure prediction Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring.	
Unit-V	Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking o combinatorial libraries, input data, analyzing docking results.	
Unit-VI	Diversity of Genomes • Prokaryotic and Eukaryotic Gene Families Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications- Genetic and Physical Mapping, Integrated map, Sequence	

assembly and gene expression. Completed Genomes Bacterium, Nema	ode.
Plant and Human, Evolution of Genomes Lateral or Horizontal Tra	
among Genomes, Transcriptome and ProteomeGeneral Acc	
Phylogenetic analysis, Evolutionary Change in Nucleotide Sequences, H	Rates
and Patterns of Nucleotide Substitution, Models for Nucleotide Substitu	tion,
Construction of Phylogenetic Tree, Genome Annotation technique.	
Total Teaching hours	65

Distribution for internals	Test (CIA I + CIA II + CIA III)	Seminars	Assignment	Total marks
Marks	15	05	05	25

REFERENCES

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors

2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, CBS Publishers and

Distributors

- 3. T. E. Creighton, Protein Structure and Molecular Properties, W. H.Freeman and Company
- 4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis

of Genes and Proteins, John Wiley & Sons, Inc.

- 5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
- 6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
- 7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
- 8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
- 9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
- 10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO - Programme Outcome, CO - Course outcome, S - Strong, M - Medium, L - Low

ELECTIVE PAPER 3:BIOLOGICAL EVALUATION OF DRUG THERAPY

Paper code:

Subject:M.sc Environmental Biotechnology

Hours/Week: 5Credits: 3

Aim: To enable the students to understand the basic concepts to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

Course Objectives

- 1. To learn about the concept involved in the general concept of standardization of biological
- 2. To learn about the concept of the importance of transgenic animals and knockout animals
- 3. To develop knowledge on , the biological medicines in development of various diseases
- 4. To understand the concept of the biological evaluation of drugs in vitro and in vivo
- 5. To develop a piece of knowledge about drug therapy of biological medicines.

Course Out Comes

6.After completing unit 1, the students will be able to know about the importance of biological and evaluation of drug therapy of biological medicines.

7. After completing unit 2, the students will be able to know the t the general concept of standardization of biological.

8. After completing unit 3, the students will be know the the importance of transgenic animals and knockout animals

9. After completing unit 4, the students will be know about the biological medicines in development of various diseases.

10..After completing unit 5, the students will be know about Biological evaluation of drugs in vitro and in vivo

11..After completing unit 6, the students will be known about Pharmacokinetics

Unit	i. Remembering	ii. Understanding	iii. Applying	iv. Analyzing	v. Evaluating	vi. Creating
1	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes	Yes	No
3	No	Yes	No	Yes	Yes	Yes
4	No	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes

Units	Course Contents	Teaching hours
Unit I	Biological Standardization • General principles, Scope and limitation of bio-assay, bioassay of some official drugs. • Preclinical drug evaluation • Preclinical drug evaluation of its biological activity, potency and toxicity- Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity. • Guidelines for toxicity studiesVarious guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.	12 hours
Unit-II		12 hours
Unit-III	Biologic Medicines in Development for various diseases - By Therapeutic Category a) Genetic Disorders b) Eye related Disorders c) Digestive Disorders d) Diabetes/Related Conditions e) Cardiovascular Disease f) Cancer/Related Conditions g) Blood Disorders h) Autoimmune Disorders	12 hours
Unit-IV	Biologic Medicines in Development for various diseases –by Product Category a) Antisense b) Vaccines c) Recombinant Hormones/Proteins d) Monoclonal Antibodies (mAb) 31 e) Interferons f) Growth Factors	12 hours
Unit-V	Regulatory aspects of drugs, biologics and medical devices An introduction to the regulations and documents necessary for approval of a medical product. Regulatory consideration Regulatory consideration for pre- clinical testing and clinical testing of drugs, biologics and medical devices. New Drug Applications for Global Pharmaceutical Product Approvals	12 hours
Unit-VI	Bioavailability • Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio- availability. • Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals. Pharmacokinetics Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.	
	Total Teaching hours	65

Distribution for internalsTest (CIA I + CIA II + CIA III)		Seminars	Assignment	Total marks
Marks	15	05	05	25

REFERENCES

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant

DNA Technology, International Association of Biological Standardization

2. J.H. Burn., Biological Standardization, Oxford University Press

3. Drug Discovery and Evaluation in Pharmacology assay: Vogel

4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,

5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.

Mapping with Programme Outcomes

Cos	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	S	S	S	М	М	М	М	S	S	S
CO2	М	М	М	S	S	М	S	S	М	М
CO3	М	М	М	S	S	S	S	М	М	М
CO4	S	S	S	М	М	М	S	S	М	S
CO5	М	М	М	S	М	S	М	М	S	S

PO - Programme Outcome, CO - Course outcome, S - Strong, M - Medium, L - Low

PROJECT