BASAVESHWAR ENGINEERING COLLEGE, BAGALKOTE
DEPARTMENT OF BIOTECHNOLOGY
Scheme and Syllabus
B. E. VII SEMESTER

Sl. No	Category	Subject Code	Subject Title	Credits	Hours/ Week			Examination Marks		
					L	T	P	CIE	SEE	TOTAL
1.	PCC	UBT704C	Economics and Plant Design	3	3	0	0	50	50	100
2.	PCC	UBT715C	Downstream Processing Technology	3	2	2	0	50	50	100
3.	PEC	UBT7XXE	Elective-4	3	3	0	0	50	50	100
4.	PEC	UBT7XXE	Elective-5	3	3	0	0	50	50	100
5.	HSMS	UBT716H	Industrial Management and Entrepreneurship	3	3	0	0	50	50	100
6.	OEC	UBT733N	Industrial Safety (Open Elective)	3	3	0	0	50	50	100
7.	INT	UBT711I	Industrial Internship	2	0	0	4	50	50	100
8.	PCCL	UBT710L	Bioseparation Techniques Lab	1	0	0	2	50	50	100
Total				**21**	**18**	**0**	**06**	**400**	**400**	**800**

Elective-4 & Elective-5

UBT722E: Biopython
UBT723E: Industrial BT
UBT724E: Food Processing Technology
UBT725E: Protein Engineering and Drug Design
UBT731E: Nanobiotechnology & Biomaterials
UBT732E: Computational Biology
UBT733E: Bioconjugative Technology
UBT734E: Food Biotechnology

UBT704C	ECONOMICS & PLANT DESIGN	Credits: 3:
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week:03		SEE Marks: 50

UNIT-I	10 Hrs.

Process design development

Design project procedure, design information from the literature and other sources of information, flow diagrams, preliminary design and equipment design and specialization, safety factors specifications, and materials of construction.

General design considerations:

Marketability of the product, availability of technology, raw materials, human resources, land and utilities, site characteristics, plant location, plant layout, plant operation and control, utilities, storage, materials handling, materials and fabrication selection,. Waste disposal community factors. Safety and hazard control measures.

UNIT–II	12Hrs.

Capital investments

Fixed capital investments including land, building, equipment and utilities, installation costs,(including equipment, instrumentation, piping, electrical installation and other utilities),working capital investments.

Manufacturing costs and plant overheads:

Manufacturing Costs: Direct Production costs (including raw materials, human resources, maintenance and repair, operating supplies, power and other utilities, royalties, etc.), fixed charges Plant Overheads: Administration, safety and other auxiliary services, Conceptual numerical.

UNIT–III	10 Hrs.

Cost analysis

Cost Analysis: Factors involved in project cost estimation, methods employed for the estimation of the capital investment. Estimation of working capital

Depreciation: different type of depreciation methods of and calculations, Conceptual numerical.

UNIT–IV	10 Hrs.

Profitability analysis

Methods for the evaluation of profitability. Return on original investment, interest rate of return, Cash flow diagrams. Break-even analysis. Conceptual numericals.

REFERENCE BOOKS*

- Peters and Timmerhaus (1989) Plant Design and Economics for Chemical Engineers, 4th edn.McGraw Hill.
- Rudd and Watson (1987) Strategy of Process Engineering, Wiley.
- Poornima M C (2006) Entrepreneurship Development and Small Business Enterprises", Pearson education.
- Vasanth Desai (2007) Dynamics of Entrepreneurial Development & Management",H imalaya Publishing House.
- Khanka SS (2004) Entrepreneurship Development, S Chand & Co.

Thomas W. Zimmer, Norman M. Scarborough.(2007), Essentials of Entrepreneurship and small Business Management

COURSE OUTCOMES**

At the end of the course the student should be able to:

1. Acquire knowledge in the design of a plant.
2. Conduct preliminary feasibility study of the plant design assigned.
3. Estimate the cost analysis involved in the design of a chemical plant.
4. Analyze the project profitability and alternative investments for the selection of good investment projects
5. Develop entrepreneurs with substantial knowledge in engineering concepts.
6. Apply the knowledge of plant design and cost estimation in actual engineering problems.

Course Outcomes	Programme Outcomes												Programme Specific Outcomes		
	1	2	3	4	5	6	7	8	9	10	11	12	PSO1	PSO2	PSO3
CO 1	2	2	1	1			1	1	1		2		2		
CO 2	2	1	2	1			1	1	1		3		2		
CO 3	1	2	1	2			1	1	1		2		1		
CO 4	2	1	2	2			1	1	1		3		2		
CO 5	1	1	2	1			1	1	1		2		1		
CO 6	2	2	2	1			1	1	1		2		2		

UBT715C	DOWNSTREAM PROCESSING TECHNOLOGY	Credits: 3
L: T: P – 2-2-0		CIE Marks: 50
Total Hours/Week: 04		SEE Marks: 50

UNIT-I	10 Hrs.

Introduction

Role and importance of downstream processing in biotechnological processes. Range and characteristics of bioproducts. Purification process of bio-product. Cell disruption methods for intracellular products; physical, chemical and mechanical methods. Basic principles of distillation,crystallization, centrifugation, ultracentrifugation (preparative and analytical).Types of centrifuges and rotors,centrifugation-differential,density gradient (zonal and isopycnic).

UNIT–II	12Hrs.

Primary Recovery Operations

Process involved in liquid-liquid extraction, solid-liquid extraction, ammonium sulphate precipitation, Precipitation of proteins and nucleic acids by solvents and polyethylene glycol, dialysis, electrodialysis, ultrafiltration (Removal of insolubles by filtration), reverse osmosis, drying and lyophilization. Membrane based separations theory, design and configuration of membrane separation equipment.

UNIT–III	10 Hrs.

Chromatography

Principles of chromatographic seperations, Classification of chromatography- plain and column chromatography, Paper chromatography - Single dimensional (Ascending and Descending, radial and two dimensional) chromatography, partition coefficient, retention factor, Thin layer chromatography, Gas liquid Chromatography, Adsorption Chromatography: Adsorption column chromatography, Ion Exchange Chromatography: cation Exchange and anion Exchange chromatography. Gel Filtration Chromatography, Affinity Chromatography, High Performance liquid chromatography, NP-HPLC and RP-HPLC.

UNIT–IV	10 Hrs.

Electrophoresis

Electrophoresis principles, factors affecting electrophoresis mobility, Moving boundary electrophoresis, Zone Electrophoresis, Gel Electrophoresis, Continuous Gel electrophoresis, Disc Gel electrophoresis, Agarose Gel Electrophoresis, Capillary Electrophoresis,Cellulose Acetate, Starch Gel , Native and SDS-PAGE, High voltage electrophoresis, Isoelectric focusing, Immunoelectrophoresis, ELISA, Flow cytometry.

Downstream Processes

Case studies (production)-DSP flowsheets for penicillin, insulin, amino acid, monoclonal antibody.

REFERENCE BOOKS*

1. BioseparationsPrinciples and techniques, by B.Sivasankar, Kindle edition,PHI Publishers, 2010
2. Biophysical chemistry principles and Techniques by Upadhay and Nath,Himalaya Publishing House, 3rd edition, 2010
3. NPTEL Source material.
4. Bioseparations - Downstream processing for biotechnology by Belter P.A., Cussier E. and Wei Shan Hu., Wiley Interscience Pub, 1988
5. Separation Processes in Biotechnology by Asenjo J. and Dekker M, 1993.
6. Product Recovery in Bioprocess Technology – BIOTOL Series, VCH, 1990
7. Rate controlled separations by Wankat P.c., Elsevier, 1990
8. Fermentation & Enzyme Technology by D.I.C. Wang, Wiley Eastern 1979

COURSE OUTCOMES**

1. Identify the basic separation unit operation in DSP like membrane separation, enrichment operation, product recovery and various resolutions and fractionation techniques.
2. Interpret and analyze the industrial fermentation processes.
3. Apply the knowledge in identifying various pharma and R&D sections.
4. Analyse the details of experimentation pertaining to chromatography and electrophoresis.
5. Understand analyse and apply the techniques in various tests involved in finding out purity of biological components.
6. Apply the knowledge in identifying various biochemicals using advanced purifications like HPLC and to demonstrate DSP flowsheets.

Course Outcomes	Programme Outcomes												Programme Specific Outcomes		
	1	2	3	4	5	6	7	8	9	10	11	12	PSO1	PSO2	PSO3
CO 1			2			3	2	2				1	2	1	1
CO 2			2			3	2	3				1	2	1	1
CO 3			1			3	2	2				1	2	1	1
CO 4			2			3	2	2				1	2	1	1
CO 5			1			3	3	3				1	2	1	1
CO 6			1			3	2	2				2	2	1	1

UBT716H	**INDUSTRIAL MANAGEMENT AND ENTREPRENEURSHIP**	**Credits: 03**
L:T:P – 3:0:0		**CIE Marks: 50**
Total Hours/Week: 03		**SEE Marks: 50**

UNIT-I	12 Hrs.

Development of management thoughts and its functions

Concept & definition of Management, Social Responsibilities of Management, and Pioneers in Management: Contributions of Taylor, Henry Taylor, Gilberth& Mayo, Schools of Management thought: Management process school, Empirical School, Human Behavior School, Social system school, Systems approach school and decision theory school. Selection of site for the plant and plant layout, plant operation and control, utilities, structural design, storage, material handling, Sources of capital. Definition and functions of administration. Planning, organizing, staffing, directing and controlling. Concept of authority and responsibility.

UNIT–II	10 Hrs.

Quantitative techniques in managerial decisions

Concept of productivity, measuring productivity, concept of budget, effective budgetary control, ABC analysis, break even analysis, product life cycle, promotion of sales, pricing, "EOQ"model. Production costs (including raw materials, and repair, operating supplies, power and other utilities, royalties, etc.), fixed charges (including depreciation, taxes, insurance, rental costs etc.).

UNIT–III	10 Hrs.

Production And Material Management

Types of production, types of planning, manufacturing planning, factory planning, production planning, method study, systems of wage payments, bonus, automation, organization of production, planning. Functions of purchasing & materials management, quality, quality standard & inspection, sources of supply, pricing, principles & practices, Inventory management.

UNIT–IV	10 Hrs.

Entrepreneurship& personnel management

Meaning of entrepreneur, evaluation of the concept, function of entrepreneur, evolution of entrepreneurship, development of entrepreneurship, stages in entrepreneurial process, role of entrepreneurs in economic development entrepreneurship- its barriers. Recruitment and selection. Training of personnel. Employer - Employee relationship. Settlement of disputes.

Reference Books *

1. O.P. Khanna - "Industrial Engineering & Management", Dhanpat Rai & Sons, 1992.
2. T. R. Banga & S. C. Sharma - "Industrial Engineering & Management Science", 6th. Edn, Khanna Publications, 2003.
3. C.B.Mamoria and S.V.Gankar- Personnel Management, Himalaya Pub, 21 st edn,2010
4. Veerabhadra Havinal -Management and Entrepreneurship- New Age International, 2009
5. Ramesh Burbure – Management &Entrepreneurship- Rohan Pub. 2008
6. Poornima M. Charanthimath – Entrepreneurship Development, Pearson Education-2005

COURSE OUTCOMES**

After completion of the course student will be able to

1. Recall and recollect the history theories and definition of management and its importance in society

2. Analyze and apply the basic concepts of Quantitative techniques of management
3. Know the difference between production and productivity, measurement and cost analysis
4. Explore the knowledge of production costs, planning and material management
5. Make basic economic analysis of project
6. Understand the role and importance of entrepreneurship in economic development

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	-	-	-	-	-	-	1	-	-	-	3	1	-	-	2
CO2	-	1	-	-	-	-	-	-	-	-	3	1	-	-	2
CO3	-	1	-	-	-	-	-	-	-	-	3	1	-	-	2
CO4	-	1	-	-	-	-	-	-	-	-	3	1	-	-	2
CO5	-	1	-	-	-	-	-	-	-	-	3	1	-	-	2
CO6	-	1	-	-	-	-	-	-	2	-	3	1	-	-	2

UBT710L	BIOSEPARATION TECHNIQUES LAB	Credits: 1
L: T: P – 0-0-2		CIE Marks: 50
Total Hours/Week: 2		SEE Marks: 50

LIST OF EXPERIMENTS

1. Cell disruption techniques.
2. Solid-liquid separation methods: Filtration (Cross flow)
3. Solid-liquid separation methods: Sedimentation.
4. Solid-liquid separation methods: Centrifugation.
5. Membrane dialysis
6. Product enrichment operations: Precipitation – (NH4)2 SO4 fractionation of a protein.
7. Product enrichment operations: Two – phase aqueous extraction.
8. Product drying techniques.
9. Estimation of Amino acids / Carbohydrates by TLC.
10. Separation of ethanol from fermented broth.
11. Separation of Citric acid from fermented broth.
12. Separation of proteins by molecular sieving.
13. Analysis of biomolecules by HPLC / GC (using standard spectra).

REFERENCE BOOKS**

1. Protein Purification by Scopes R.K., IRL Press,1993.
2. Rate controlled separations by Wankat P.C., Elsevier, 1990
3. Bioseparations by Belter P.A. and Cussier E., Wiley, 1985.
4. Bio-separations Science & Engineering By Roger G Harrison, Paul Todd, Scott R Rudge, Demetri.
5. Product Recovery in Bioprocess Technology - BIOTOL Series, VCH, 1990
6. Separation processes in Biotechnology by Asenjo J. and Dekker M. 1993

COURSE OUTCOMES**

1. Able to prepare/reproduce the protocols for the experiments.
2. Able to extract the intracellular product using different cell disruption techniques.
3. Able to concentrate, purify the desired product using different chromatography/ filtration techniques.
4. Able to analyze the product both quantitative/qualitatively.
5. Able to record/observe the experimental data and interpret them in the graph/table.
6. Able to calculate the result and to write the conclusion at the end of the experiment.

Course Outcomes	Programme Outcomes												Programme Specific Outcomes		
	1	2	3	4	5	6	7	8	9	10	11	12	PSO1	PSO2	PSO3
CO 1	3												3		1
CO 2		2												3	1
CO 3			3										2	2	1
CO 4				3	3								2	2	1
CO 5		3										2	2	3	1
CO 6		3										2	3	2	1

UBT722E	Biopython	Credits: 03
L:T:P - 3 : 0: 0		CIEMarks:50
Total Hours/Week: 03		SEEMarks:50

UNIT-I	16 Hrs.
Introduction and brief history of Biopython, Biopython modules, Tools and GNU/Linux, Nucleic Acid Bioinformatics, Sequences, Strings, and the Genetic Code, Sequences File Formats, Introduction to Biological Sequence Database, Sequence Motifs, Introduction to Motifs, String Matching, Consensus Sequences, Motif Finding, Promoters, De novo Motif Finding.	
UNIT–II	**12 Hrs.**

Sequence Alignments, Alignment Algorithms and Dynamic Programming, Alignment Software, Alignment Statistics, Short Read Mapping Multiple Sequence Alignments, Molecular Evolution, and Phylogenetics, Multiple Sequence Alignment, Phylogenetic Trees, Models of mutations,

Practices
Lab 4: Using BLAST on the command line, Lab 5: Phylogenetics

UNIT–III	12 Hrs.

Genomics, The Three Fundamental "Gotchas" of Genomics, Genomic Data and File Formats, Genome Browsers, Transcriptomics, High-throughout Sequencing (HTS), RNA Deep Sequencing, Small RNA sequencing, Long RNA sequencing, Single-Cell Transcriptomics, Transcription Initiation, Transcription, Elongation, RNA Seq, Noncoding RNAs, Small Noncoding RNAs (srcRNAs), Long Noncoding RNAs, RNA Structure Prediction, Destabilizing energies.

Practices: Lab 6: Genome Annotation Data, Lab 7: RNA-seq, Lab 8: RNA Structure,

Lab 9: Proteins.

UNIT–IV	12 Hrs.

Protein Alignment, Functional Annotation of Proteins, Secondary Structure prediction, Gene Ontology, Gene Regulation, Transcription Factors and ChIP-seq, MicroRNA regulation and Small RNA-seq, Regulatory Networks.

Practices: Lab 8: RNA Structure, Lab 9: Proteins, Lab 10: ChIP-seq

Reference Books *

Reference Books:

1) Prof. David A. Hendrix
2) Deep Learning with Python, Francois Chollet

Reference Books/Protocols: Tutorials Point (Simply easy learning).

Course Outcomes**

After completion of the course student will be able to

1,Obtain knowledge on the biopython-GNU/Linux, modules, tools, commands and Motifs.
2.Acquire the skills of Sequence Alignments using the Softwares, Statistics, Short Read Mapping, Multiple Sequence Alignments, Molecular Evolution,
3.Understand and Analyze the Phylogenetics, Phylogenetic Trees, and Models of mutations.
4.Utilize the biopython in analysis of the Genomic and transcriptomics data.
5. Conduct the Protein Alignment, Functional Annotation, Secondary Structure prediction, Gene Ontology, Gene Regulation.

UBT724E	FOOD PROCESSING TECHNOLOGY	Credits: 3
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week: 03		SEE Marks: 50

UNIT-I	10 Hrs.

Introduction

Constituents of food, soluble fibres, protein rich foods, popular fats and oils in foods, Food flavours, Browning reactions and its effects . Intrinsic and extrinsic parameters of foods, effect of inhibitors, pH and temperature. Minerals in foods. Aroma compounds in foods .Food additives, Vitamins, amino acids, Sweeteners, Food colours. Toxic-trace elements in food.

UNIT–II	12Hrs.

Detection of Microorganisms

Culture, Microscopic and Sampling Methods, Conventional; SPC, Membrane Filters, Microscope colony Counts, Agar Droplets, Dry Films, Most probable Numbers (MPN), Dyereduction, Roll Tubes, Direct, Microscopic Count (DMC), Microbiological Examination of surfaces, Air Sampling, Metabolically Injured Organisms, Enumeration and Detection of Food-borne Organisms. Dairy products: Composition of milk, Sterilization of milk (Pasteurization and UHT), Cheese production, Acidophilus milk Yoghurt, Kumiss and Kefir. Marketing scope of dairy & food products Fruit and vegetable processing: Jam, jelly, Juice, squash, wine, pickles and sauerkraut

UNIT–III	10 Hrs.

Food Spoilage & Preservation

The Role and Significance of Microorganisms, Primary Sources of Microorganisms found in Foods Synopsis of common borne bacteria, Molds& Yeasts. Microbial Spoilage of Vegetables, Fruits, Fresh and Processed Meats, Poultry, and Seafood. Spoilage of Miscellaneous Foods, Food Preservation: Principles Underlying in spoilage and preservation, Application, Effect and Legal Status of Food Irradiation, Food Preservation with Low Temperatures, High Temperatures and Drying. Food Industry: Characteristics of Food Industry.:, nutritional food supplements. Food packaging, New trends in packing, edible films. Factors influencing food product development, marketing, and promotional strategies, risks and benefits of food industry.

UNIT–IV	10 Hrs.

Food Engineering

Properties of fluid foods, Measurement of rheological parameters .Thermal properties of frozen foods. Food freezing equipment, storage of frozen foods. Food dehydration: Freeze Dehydration Calculation of drying times. Food waste management.

REFERENCE BOOKS*

1. Food Science & Nutrition, by Sunetra Roady, Oxford University Press,2007.
2. Food microbiology by William Frazier and Westhoff D.C, 4thEdn,TATA McGraw Hill Pub(2005)
3. Modern Food Micro-Biology by James M.Jay, CBS Publishers.2005.
4. Food Microbiology by K.Vijay RameshMJP Publishers, 2007.
5. Plant biotechnology In Agriculture by K. Lindsey and M.G.K. Jones, Prentice Hall, USA. 1990.
6. Food Science By Potter N.N. and Joseph Hotchkiss, 5thEdn, CBSPub,1996.

COURSE OUTCOMES**

1. Able to know about basic constituents of food
2. Able to know the techniques involved in detection of microbes in food industry
3. To have idea about Dairy , fruits and vegetable processed products and production
4. To be aware of different food spoilage and preservation techniques
5. To know the Characteristics of food industry and scope
6. Able to understand Basic concepts in food Engineering for preservation

Course Outcomes	Programme Outcomes	Programme Specific Outcomes

	1	2	3	4	5	6	7	8	9	10	11	12	PSO1	PSO2	PSO3
CO 1			2			3	2	2				1	2	1	
CO 2			2			3	2	3				1	2	1	
CO 3			1			3	2	2				1	2	1	
CO 4			2			3	2	2				1	2	1	
CO 5			1			3	3	3				1	2	1	
CO 6			1			3	2	2				2	2	1	

UBT725E	**PROTEIN ENGINEERING AND DRUG DESIGN**	**Credits: 03**
L:T:P – 3:0:0		**CIE Marks: 50**
Total Hours/Week: 03		**SEE Marks: 50**

UNIT-I	**10 Hours**

Structure of proteins

Overview of protein structure, PDB, structure based classification, databases, visualization tools, structure alignment, domain architecture databases, protein-ligand interactions.

Protein structure prediction

Primary structure and its determination, secondary structure prediction and determination of motifs, profiles, patterns, fingerprints, super secondary structures, protein folding pathways, tertiary structure, quaternary structure, methods to determine tertiary and quaternary structure, post translational modification.

Protein engineering and design

Methods of protein isolation, purification and quantitation; large scale synthesis of proteins, design and synthesis of peptides, use of peptides in biology, methods of detection and analysis of proteins. Protein database analysis, methods to alter primary structure of proteins, examples of engineered proteins, protein design, principles and examples.

UNIT–II	10 Hrs.

Molecular modeling

Constructing an Initial Model, Refining the Model, Manipulating the Model, Visualization. Structure Generation or Retrieval, Structure Visualization, Conformation Generation, Deriving Bioactive Conformations, Molecule Superposition and Alignment, Deriving the Pharmacophoric Pattern, Receptor Mapping, Estimating Biological Activities, Molecular Interactions: Docking, Calculation of Molecular Properties, Energy Calculations (no derivation), Examples of Small Molecular Modeling Work, Nicotinic Ligands, Sigma Ligands, Antimalarial Agents.

UNIT–III	10 Hrs.

Insilico drug design

Generation of Rational Approaches in Drug Design, Molecular Modeling: The Second Generation, Conceptual Frame and Methodology of Molecular Modeling, The Field Currently Covered, Importance of the "Bioactive Conformation", Molecular Mimicry and Structural Similarities, Molecular Mimicry, Structural Similarities and Superimposition Techniques, Rational Drug Design and Chemical Intuition, An Important Key and the Role of the Molecular Model, Limitations of Chemical Intuition Major Milestones and Future Perspectives.

Computer assisted new lead design

Introduction, Basic Concepts, Molecular Recognition by Receptor and Ligand Design, Active Conformation, Approaches to Discover New Functions, Approaches to the Cases with known and unknown receptor structure.

UNIT–IV	10 Hrs.

Docking methods

Program GREEN Grid: Three -Dimensional Description of Binding Site Environment and Energy Calculation, Automatic Docking Method, Three-Dimensional Database Search Approaches, Automated Structure Construction Methods, Structure Construction Methods with known Three-Dimensional Structure of the Receptor, Structure Construction in the case of Unknown Receptor Structure. Scope and Limitations, Points for Consideration in Structure, Construction Methods, Handling of X-Ray Structures of Proteins, Future Perspectives, Types of programs available for molecular modeling-scope and limitations-interpretation of results.

Computer - assisted drug discovery

The Drug Development Process, Introduction, The Discovery and Development Process, New Lead Discovery Strategies, Composition of Drug Discovery Teams, The Practice of Computer-Assisted Drug Discovery (CADD), Current Practice of CADD in the pharmaceutical Industry, Management Structures of CADD Groups, Contributions and Achievements of CADD Groups, Limitations of CADD Support, Inherent Limitations of CADD Support, State of Current Computational Models, Software and Hardware Constraints.

REFERENCE BOOKS *

1. Bioinformatics Methods & Applications: Genomics, Proteomics & Drug Discovery, S C Rastogi, Mendiratta & P Rastogi, PHI,4th Edition, 2013
2. Moody P.C.E. and A.J. Wilkinson Protein Engineering, IRL Press, Oxford, 3rd Edition,2010.
3. Creighton T.E. Proteins, Freeman W.H. Second Edn,1993.
4. Branden C. and Tooze R. Introduction of protein structure, Garland,1993.

5. The molecular modeling perspective in drug design by N Claude Cohen, 2008, Academic Press.

COURSE OUTCOMES**

1. Ability to study protein structure prediction and protein engineering and design
2. Able to understand molecular modeling
3. Able to know computer assisted new lead design
4. Able to study docking methods and computer - assisted drug discovery

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	1	-	2	-	1	1	2	2	-	-	-	1	2	1	1
CO2	1	-	2	-	-	2	2	3	-	-	-	1	2	1	2
CO3	-	-	1	1	2	-	2	2	-	-	-	1	2	1	-
CO4	2	-	2	-	-	1	2	2	-	-	-	1	2	1	-

UBT731E	NANOBIOTECHNOLOGY AND BIOMATERIALS	Credits: 03
L:T:P – 3:0:0		CIE Marks: 50
Total Hours/Week: 03		SEE Marks: 50

UNIT-I	10 Hrs.

Introduction to nanotechnology:

A Brief History of the Nano particles : Bottom-Up versus Top-Down; What Is Nanobiotechnology.Discussions on nanofabrication, nanolithography, nanotubes, buckyballs, structure-property relationships in materials, materials characterization techniques, scanning electron, scanning tunneling and atomic force microscopy(SEM,STM & AFM), biomolecule-surface interactions, quantum dots,

Applications of nanotechnology in the life sciences:

Buckyballs and Buckytubes, Diagnostics and Sensors, Drug Delivery Revenues Health Risks and Challenge.

UNIT–II	10 Hrs.

Biopolymers:

Polymers as biomaterials, microstructure, mechanical properties – effects of environment on elastic moduli,sterilization and disinfections of polymeric materials. Biocompatibility of

polymers, chemically modified glycosaminoglycans, heparin like substances from nonglycosaminoglycan polysaccharides and microbial glycosaminoglycan, surface immobilized heparins.

UNIT–III	10 Hrs.

Synthetic polymers:

Polymers in biomedical use, polyethylene and polypropylene, perfluorinated polymers, acrylic polymers, hydrogels, polyurethanes, polyamides, biodegradable synthetic polymers, silicone rubber, plasma polymerization, micro-organisms in polymeric implants, polymer sterilization.

UNIT–IV	10 Hrs.

Biocompatibility:

Definition, Wound healing process-bone healing, tendon healing. Material response: Function and Degradation of materials in vivo. Host response: Tissue response to biomaterials . Testing of implants: Methods of test for biological performance-In vitro implant tests, In vivo implant test methods.

Medical devices:

Polyurethane elastomers, applications of polymers in medicine and surgery. Skin graft polymers, Properties of implant materials, metals and alloys.

REFERENCE BOOKS *

1. B.Vishwanath (2011). " Nano Materials" Published by Narosa Publishing House Pvt. Ltd., New Delh.
2. Mark Ratner and Daniel Ratner (2003). "Nanotechnology:A Gentle Introduction to Next Gig Idea" Pearson Ecducation Ltd.
3. K Eric Drexler (1993). "Unbounding the future" Quill.
4. Stephen Lee and Lynn M Savage (2010). "Biological molecules in Nanotechnology".

COURSE OUTCOMES**

After completion of the course student will have the

1. Ability to explain the characterization techniques of nanotechnology.
2. Ability to understand the importance of nano-particles in drug delivery system.
3. Ability to understand the importance of biopolymers.
4. Ability to differentiate biopolymer and synthetic polymer.
5. Ability to understand the importance of biocompatibility.
6. Ability to apply the methods to test the implants and use in medical devices.

*** Books to be listed as per the format with decreasing level of coverage of syllabus**
**** Each CO to be written with proper action word and should be assessable and quantifiable**

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	2	3	3	-	-	1	2	-	-	-	-	-	2	2	1
CO2	1	2	3	-	-	1	-	-	-	-	-	-	3	-	-
CO3	2	2	3	-	-	2	-	-	-	-	-	-	2	2	1
CO4	3	3	3	-	-	2	-	-	-	-	-	-	2	1	1
CO5	3	3	3	-	-	1	-	-	-	-	-	1	2	-	-
CO6	2	3	3	-		3	3	-	-	-		-	3	1	-

UBT732E	COMPUTATIONAL BIOLOGY	03 - Credits (3 : 0 : 0)
Hours / Week : 03		CIE Marks : 50

Total Hours : 40		SEE Marks : 50

UNIT – 1	12 Hrs
Nature and scope of Computational Biology: Basic algorithms in Computational Biology, Biological and Computer algorithm, Fibonacci problem, Dynamic Programming, Time and space complexity of algorithms, Laplace's Rule. Search Algorithms: Random walk, Hill climbing, simulated annealing. Combinatorial Pattern Matching: Hash Tables, Repeat Finding, Exact Pattern Matching; Genetic Algorithm: Basic Concepts, Reproduction, Cross over, Mutation, Fitness Value, Optimization using GAs; Applications of GA in bioinformatics.	
UNIT – 2	**8 Hrs**
Combinatorial Pattern Matching: Hash Tables, Repeat Finding, Exact Pattern Matching; Genetic Algorithm: Basic Concepts, Reproduction, Cross over, Mutation, Fitness Value, Optimization using GAs; Applications of GA in bioinformatics.	
UNIT – 3	**10 Hrs**
Hidden Markov Model: Markov processes and Markov Models, Hidden Markov Models. Forward and Backward Algorithms, Most probable state path: Viterbi algorithm, Parameter Estimation for HMMs:-Baum-Welch Algorithm, Applications of profile HMMs for multiple alignment of proteins and for finding genes in the DNA.	
UNIT – 4	**10 Hrs**
Insilico Drug Design and Biopython applications in Computational Biology Insilico Drug Design: Basic Concepts, importance and application, Molecular force fields and energy minimization, Molecular Dynamics Simulation methods, Methods of Insilico Drug Design: structure and ligand based drug design approach, structure based drug design: Molecular docking. Biopython: Introduction, important features and application of biopython in computational biology, Create a simple sequence in Biopython for DNA, RNA and Protein Alphabets, Sequence Alignment Tools in Biopython, PDB Module of Biopython,	
REFERENCE BOOKS	

- Introduction to bioinformatics by Teresa K. Attwood, David J. Parry-Smith,1999,Pearson Education.
- Arthur M.Lesk, Introduction to Bioinformatics, Oxford University Press, New Delhi, 2003.
- Higgins and W.Taylor (Eds), Bioinformatics-Sequence, Structure and databanks, Oxford University Press, New Delhi, 2000
- An introduction to bioinformatics algorithms by Neil C. Jones, Pavel Pevzner. MIT Press.2004 2.
- Biological sequence analysis: Probabilistic models of proteins and nucleic acids by Richard Durbin, Eddy, Anders Krogh, 1998

Algorithms for Molecular Biology by Ron Shamir Lecture, Fall Semester, 20014.

1. Bioinformatics- a practical guide to the analysis of Genes and Proteins by Baxevanis, A.D. and Francis Ouellellette, B.F., 1998, John Wiley & Sons, UK.
2. Introduction to bioinformatics by Teresa K. Attwood, David J. Parry-Smith, 1999,Pearson Education.
3. Arthur M.Lesk, Introduction to Bioinformatics, Oxford University Press, New Delhi, 2003.
4. D.Higgins and W.Taylor (Eds), Bioinformatics-Sequence, Structure and databanks, Oxford University Press, New Delhi, 2000.
5. Bioinformatics: the machine learning approach by Pierre Baldi, Søren Brunak. MIT Press.2001 2.
6. Bioinformatics: Sequence and Genome Analysis: by David Mount, University of Arizona,Tucson

COURSE OUTCOMES

After completion of the course student will be able to

1) Understand the nature, scope of computational biology and biological and computer algorithms.
2) Know about the Combinatorial Pattern Matching, Genetic algorithms and their applications.
3) Analyze various Markov processes and Markov Models.
4) **Learn about the Insilico Drug Design and Biopython applications in Computational Biology**

Course Outcomes	Programme Outcomes												Programme Specific Outcomes		
	1	2	3	4	5	6	7	8	9	10	11	12	PSO1	PSO2	PSO3
CO 1	3	3	3									2	2	1	
CO 2	2	3	3									2	2	1	
CO 3	3	3	3									1	2	1	
CO 4	3	3	3									1	2	1	

UBT733E	BIOCONJUGATIVE TECHNOLOGY	Credits: 03

L:T:P – 3:0:0	CIE Marks: 50
Total Hours:40	SEE Marks: 50

UNIT-I	10 Hours

Bioconjugative technology

Modification of Amino Acids, Peptides and Proteins – Modification of sugars, polysaccharides and glycoconjugates – modification of nucleic acids and oligonucleotides.

UNIT–II	10 Hrs.

Chemistry of active groups

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

Bioconjugate reagents

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

UNIT–III	10 Hrs.

Enzyme and nucleic acid modification and conjugation

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

UNIT–IV	10 Hrs.

Bioconjugate applications

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

REFERENCE BOOKS *

1. Bioconjugate Techniques, G.T. Hermanson, Academic Press, 2 nd edition 2008
2. Bioconjugate techniques , Greg T Hermanson, academic Press ,Global store , 2016
3. A Text book of biophysics by Dr R.N. Roy,UBS publishers, 2001
4. Bioconjugative Chemistry by Vincent M Rotello, American Chemical society, 2016
5. Bioconjugate techniques , Greg T Hermanson, academic Press ,Global store , 2017

COURSE OUTCOMES**

1. Able to understand modification of nucleic acids and oligonucleotides.
2. Ability to know the chemistry of active groups.
3. To analyse the bioconjugate reactants.
4. To analyze bioconjugate applications .
5. Ability to know the conjugate derivatives.
6. Ability tostudy the conjugation process.

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3

CO1	1	-	2	-	1	1	2	1	-	-	-	1	2	1	1
CO2	**1**	-	**2**	-	-	**2**	**2**	-	-	-	-	**1**	**2**	**1**	**2**
CO3	-	-	**1**	**1**	**2**	-	**2**	-	-	-	-	**1**	**2**	**1**	-
CO4	**2**	-	**2**	-	-	**1**	**2**	**1**	-	-	-	**1**	**2**	**1**	-
CO5	-	-	**1**	**2**	**2**	-	**3**	**1**	-	-	-	**1**	**2**	**1**	**1**
CO6	**1**	-	**1**	-	-	**2**	**2**	**2**	-	-	-	**2**	**2**	**1**	-

UBT734E	**FOOD BIOTECHNOLOGY**	**Credits: 03**
L:T:P – 3:0:0		**CIE Marks: 50**
Total Hours/Week: 03		**SEE Marks: 50**

UNIT-I	**10 Hours**

Introduction

Hunger, Technology and World food needs-nutritional problems, approaches to combat world hunger, roles of technology. Recent Developments in food biotechnology, introduction to molecular food biotechnology.

Novel bioprocessing

Biosensors for food quality assessment, cold active enzymes in food processing, biotransformation in food industries.

Nutrigenomics

Definition of Nutriomics, Nutrigenetics, and its applications, Nutritional genomics and applications in brief. Nutrigenetics and cancer.

UNIT–II	10 Hrs.

Microbial biotechnology of food

Metabolic engineering of bacteria for food ingredients (Amino acids, organic acids, vitamins). Introduction to technologies for microbial production of food ingredients. Solid-state fermentation for food applications (enzymes, pigments). Biotechnology of microbial polysaccharides- natural occurrence of microbial polysaccharides in foods, additives (xanthan) and its future, Microbial biotechnology of food flavor, oils and fats. Food applications of algae-nutritional value, source of neutraceuticals and industrial production processes (chlorella, spirulina, Agar, alginate). Genetics of Dairy starter cultures.

UNIT–III	10 Hrs.

Plant food applications

Genomic basics for food improvement, molecular design of soybean proteins for enhanced food quality, Genetic modifications of plant starches, plant oils, for food applications. Bioprocessing of starch using enzyme technology. Molecular biotechnology for neutraceutical enrichment of food crops, Biotechnology of nonnutritive sweeteners, metabolic redesign of vitamin -E biosynthesis, production of new metabolites, Engineering of provitamin- A ,biosynthetic pathway into rice(Golden rice), Engineering of carotenoid biosynthesis for antioxidants, approaches to improve nutritional quality and shelf life of fruits and vegetables.

UNIT–IV	10 Hrs.

Enhancement of leaf quality protein for ruminant animals. Methods of chloroplast transformation, markers for transformation, engineering chloroplast for the production of edible vaccine, Transplastomic maize- a case study.

Animal food applications: Genetic modification of production traits in farm animals, Foods made from GM animals, applications of transgenic fish technology in sea food production, enzymatic synthesis of oligosaccharides-progress and recent trends.

Food safety: international aspects of the quality and safety, genetically modified food controversies. Regulation of the release of genetic modified organisms,patenting inventions in food biotechnology.

REFERENCE BOOKS *

1. Kalidas s, Gopinadhan P, Anthony P and Robert E.Levin- " Food Biotechnology"- second edition, CRC press, 2006
2. Gustavo F.G and Gustavo V.B,-" Food Science and Food Biotechnology"- CRC press, 2003
3. Mahesh S.-" Plant Molecular Biotechnology"- first edition, New age international publishers, , 2008

4. Norman N.Potter and Joseph H. Hotchkiss- Food Science- fifth edition- CBS publishers and distributors, 2007

COURSE OUTCOMES**

1. Students will be able to know the importance and current status of food biotechnology
2. Students will acquire the knowledge on novel food bioprocessing, nutrigenomics in brief.
3. Explore the applications of microbes in food biotechnology, new sources of food from microbes etc
4. Will be able to learn about plant food biotechnology and transplastomic technology
5. Will get the knowledge on applications of Animal food biotechnology and food safety and its regulation
6. Able to have an overview recent trends in GMOs and food biotechnology

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	1	1	2	-	2	1	-	-	-	-	-	1	2	1	1
CO2	2	-	2	-	3	2	-	-	-	-	-	1	2	1	1
CO3	1	1	1	-	2	2	-	-	-	-	-	1	2	1	2
CO4	2	-	2	-	2	1	-	-	-	-	-	1	2	1	1
CO5	2	1	1	-	3	1	-	-	-	-	-	1	2	1	2
CO6	1	-	1	-	2	2	-	-	-	-	-	2	2	1	1

UBT733N	INDUSTRIAL SAFETY	Credits: 03
L:T:P – 3:0:0		CIE Marks: 50
Total Hours/Week: 03		SEE Marks: 50

UNIT-I	12 Hrs.

Industrial safety

Need for safety, importance of occupational health and safety, Health and safety programs, unsafe conditions, factors contributing to unsafe conditions, Good Lab Practices (GLP).

Accidents:
Accident preventive measure, Measurement and control of safety performance, 5E's for accident prevention- Engineering, Education, Enthusiasm, Enforcement and Evaluation. Hierarchy of Controls, Safety policy.
Chemical Hazards:
Types of hazards, Classification of chemicals based on their nature, routes to exposure of chemicals, Health effects of harmful chemicals in the work environment, Control of chemical hazards.

UNIT–II	10 Hrs.

Electrical Hazards and Control measures
Electrical hazards, protection against voltage fluctuations, effects of shock on human body. Fire- Fire formation, Fire extinguishing agents. Evacuation procedures for workers during emergency conditions.
Physical Hazards and Control measures:
Noise, noise exposure regulation, properties of sound, Workers exposure to electromagnetic field, Ionizing radiation and non-ionizing radiations, effects of radiations, Classification of dangerous materials with pictorial symbols, Safety in transportation of dangerous materials by road, rail, ships and pipelines.

UNIT–III	10 Hrs.

Biological and Construction Hazards and their control measures
Classification of Bio hazardous agents –bacterial agents, rickettsial and chlamydial agents, viral agents, fungal, parasitic agents, infectious diseases –Hazardous material used in labs, Instructions followed for hazardous waste disposal, Biohazard control program, Biological safety cabinets.
Construction Hazards:
Hazards in construction and safety measures, Good Manufacturing Practices (GMP).

UNIT–IV	10 Hrs.

Occupational Health and Toxicology
Classification of Occupational hazards, occupational related diseases- silicosis, asbestosis, pneumoconiosis, etc. lead, nickel, chromium and manganese toxicity, effects and prevention Industrial toxicology, local, systemic and chronic effects, temporary and cumulative effects. Industrial Hygiene. Various types of Company policies.

REFERENCE BOOKS *

1. Mark Friend and James Kohn, (2007), Fundamentals of Occupational Safety and Health The Scarecrow Press, Inc.
2. Phil Hughes and Ed Ferret, (2011), Introduction to Health and Safety at work, (5th edition), Elsevier Ltd.

COURSE OUTCOMES**

After completion of the course student will be able to
1. Analyze the effects of hazards in workplace and select appropriate measures of safety for preventing industrial accidents and chemical hazards.
2. Identify physical and electrical hazards and apply control measures in work place for the prevention of fires and explosions.
3. Identify various types of biological hazards and understand the methods of hazard identification and preventive measures.

4. Assess the risks in the occupation, identify control measures and apply hygiene in the work place.

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	-	1	2	-	1	3	-	-	-	-	-	1	1	1	1
CO2	-	1	2	-	1	3	-	-	-	-	-	1	1	1	1
CO3	-	1	2	-	1	3	-	-	-	-	-	1	1	1	1
CO4	-	1	2	-	1	3	-	-	-	-	-	1	1	1	1

B. E. VIII SEMESTER

Sl. No	Category	Subject Code	Subject Title	Credits	Hours/ Week			Examination Marks		
					L	T	P	CIE	SEE	TOTAL
1.	PEC	UBT82XE	Elective-6	03	3	0	0	50	50	100
2.	PEC	UBT83XE	Elective-7	03	3	0	0	50	50	100
3.	PP	UBT805P	Project	15	0	0	30	50	50	100
Total				**21**	**6**	**0**	**30**	**150**	**150**	**300**

Elective-6
UBT823E: Biosimulations
UBT824E: Metabolic engineering

UBT825E: Bionanalytical techniques
UBT827E: Pharmaceutical BT

Elective-7
UBT830E: Clinical research
UBT832E: Health diagnostics
UBT833E: Validation & quality control
UBT834E: Product development
UBT835E: Validation & quality assurance

UBT823E	**BIOSIMULATIONS**	**Credits: 03**
L:T:P – 3:0:0		**CIE Marks: 50**
Total Hours/Week: 03		**SEE Marks: 50**

UNIT-I	**08 Hours**
Modelling Principles: Basic modeling principles, uses of mathematical modeling classification of modeling techniques Fundamental laws, energy equations, continuity equation, equations of motion, transport equations, equations of state, equilibrium states and chemical kinetics-examples.	
UNIT–II	**08 Hrs.**
Mathematical Models for Biochemical Engineering Systems: Mathematical models for Biochemical engineering systems, Mathematical models in batch and continuous process, continuous flow tanks, reversible reaction.	
UNIT–III	**16 Hrs.**
Simulation Softwares in Bioprocess: Introduction to SuperPro Designer for Material balance, Software for mass and energy balance; Energy Balance with and without reaction. **Metabolic Flux** Balance Analysis: Introduction, Principle of steady state metabolic flux balance analysis, COPASI, COBRA.	
UNIT–IV	**08Hrs.**

Matlab and Simulink: MATLAB for data analysis Basics, Data analysis, curve fittings, Numerical integration, Euler and fourth order RungeKutta method, Simulation of gravity flow tank, SIMULINK for dynamic systems.

REFERENCE BOOKS *

1. Luben W.L. "Process Modelling Simulation and Control for Chemical Engineers", McGrawHill, International New York, 1990.
2. Franks RGE. "Mathematical Modeling in Chemical Engineering", John Wiley and Sons, Inc., New York, 2004.
3. Biquette W.B. "Process Dynamics- Modeling analysis with simulation", Prentice Hall; 1 edition January 15, 1998.
4. William J. Palm. "Introduction to Matlab 7 for Engineers", III, McGraw Hill 2005.
5. Kenneth J. Beers. "Numerical Methods for Chemical Engineering Applications in MATLAB", Massachusetts Institute of Technology, Cambridge University press 2007 edition.
6. http://www.mathworks.com

COURSE OUTCOMES**

Course Outcomes: After the completion of this course, students will be

1) Analyse the biological and bioprocess data and make suitable interpretation of them.
2) Handle mathematical models
3) Understand simulation software's for bioprocess development.
4) Analyze using Matlab and Simulink

UBT824E	METABOLIC ENGINEERING	Credits: 03
L:T:P – 3:0:0		CIE Marks: 50
Total Hours/Week: 03		SEE Marks: 50

UNIT-I	10 Hours

Introduction

Basic Concept of metabolic engineering overview of metabolism. Different models for cellular reactions, Mutation, mutagens mutation in metabolic studies.

Metabolic regulation

An overview of Cellular Metabolism, Transport Processes, Passive Transport, Facilitated Diffusion, Active Transport, Fueling Reactions, Glycolysis, ermentative Pathways, TCA Cycle and Oxidative Phosphorylation, Anaplerotic Pathways, atabolism of Fats, Organic Acids, and Amino Acids, Biosynthetic Reaction, iosynthesis of Amino Acids, Biosynthesis of Nucleic Acids, Fatty Acids, and Other Building Blocks, Polymerization, Growth Energetics

UNIT–II	10 Hrs.

Metabolic flux

Metabolic flux analysis and its application, Methods for experimental determination of metabolic flux by isotope dilution method.

Applications of metabolic flux analysis

Amino Acid Production by Glutamic Acid Bacteria, Biochemistry and Regulation of Glutamic Acid Bacteria, Calculation of Theoretical Yields, Metabolic Flux Analysis of Lysine Biosynthetic Network in C. glutamicum, Metabolic Flux Analysis of Specific Deletion Mutants of C. Glutamicum, Metabolic Fluxes in Mammalian Cell Cultures, Determentation

of Intracellular Fluxes., Computational Networks and Systems Biology

UNIT–III	10 Hrs.

Regulation of metabolic pathways

Regulation of Enzymatic Activity, Overview of Enzyme Kinetics, Simple Reversible Inhibition Systems, Irreversible Inhibition, Allosteric Enzymes: Cooperativity, Regulation of Enzyme Concentration, Control of Transcription Initiation, Control of Translation, Global Control: Regulation at the Whole Cell Level, Regulation of Metabolic Networks, Branch Point Classification, Coupled Reactions and the Role of Global Currency Metabolites.

UNIT–IV	10 Hrs.

Metabolic engineering in practice

Enhancement of Product Yield and Productivity, Ethanol, Amino Acids, Solvents, Extension of Substrate Range, Metabolic Engineering of Pentose Metabolism for Ethanol Production, Cellulose-Hemicellulose Depolymerization, Lactose and Whey Utilization, Sucrose Utilization, Starch Degrading Microorganisms, Extension of Product Spectrum and Novel Products, Antibiotics, Polyketides, Vitamins, Biopolymers, Biological Pigments, Hydrogen, Pentoses: Xylitol, Improvement of Cellular Properties, Alteration of Nitrogen Metabolism, Enhanced Oxygen Utilization, Prevention of Overflow Metabolism, Alteration of Substrate Uptake, Maintenance of Genetic Stability, Xenobiotic Degradation, Polychlorinated Biphenyls (PCBs), Benzene, Toluene, P-Xylene Mixtures (BTX).

REFERENCE BOOKS *

1. P.F. Stanbury and A. Whitkar. 2008,Principle of Fermentation Technology pergaman press,
2. Wang D I C Cooney C I Demain, A L ,2008, “Fermentation and enzyme Technology” John Willey,
3. Roberts, 2007 “Metabolism of Agrochemicals in Plants” Willey Int,.
4. David L. Nelson and Michael Cox, 2016, “Lehninger Principles of Biochemistry” –6th Edition
5. Lubert Stryer, 2010 “Biochemistry” -Freeman & Co., Pub.

COURSE OUTCOMES**

1. Recall the concepts of cellular metabolism.
2. Explain the Basic concepts of metabolic engineering.
3. Explain Fundamentals of Metabolic flux analysis.
4. Apply the knowledge of metabolic flux analysis.
5. Apply the knowledge of regulatory mechanism for altering the metabolic pathways.
6. Design the metabolic pathways for desired product.

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	2	2	2			2							1	1	1
CO2	2	2	2		2	3							2	1	2
CO3	3	3	2		2	2						1	1	1	2
CO4	3	3	3		2	3						1	2	1	3

CO5	2	1		2		2		2					1	3	1
CO6	1	2	3	2		3		1					1	3	1

UBT825E	BIOANALYTICAL TECHNIQUES	03 - Credits (3 : 0 : 0)
Hours / Week : 03		CIE Marks : 50
Total Hours : 40		SEE Marks : 50

UNIT – 1	10 Hrs.

Centrifugation

Introduction: Basic, Types of centrifuges: Desktop, High Speed and Ultracentrifuge (Preparatory and Analytical), Design and their working principle, Types of Rotors, Wall-effect

Spectroscopy :

(i) Absorption Spectroscopy

Simple theory of absorption of light by molecules, Chromophore and terminologies associated with absorption of molecules

The Beer-Lambert Law and its deviations

Single and double beam spectrophotometers for measuring Visible and Ultraviolet light: Instrumentation and Parameters measured in absorption Spectroscopy **(UV-Vis spectrophotometer)**

Empirical rule for the absorption spectra of biological macromolecules

Chemical Analysis by absorption spectroscopy using Visible and Ultraviolet light

(ii) Fluorescence Spectroscopy

Simple theory of Fluorescence

Instrumentation and Technology of Fluorescence Spectroscopy **(Fluorescence spectrometer)**

Intrinsic Fluorescence measurements for information about the conformation and binding sites of proteins

Extrinsic fluorescence measurements for information about the conformation and binding sites of proteins

UNIT – 2	10 Hrs.

(iii) Infrared Spectroscopy

Infrared Spectroscopy: Basic Principle Instrumentation and Technology of Infrared Spectroscopy (Fourier-transform infrared spectroscopy (FTIR))

Information in Infrared Spectra and Applications of Infrared spectroscopy

(iv) Optical Rotatory Dispersion (ORD) & Circular Dichroism (CD)

Theory of Optical Rotatory Dispersion (ORD) & Circular Dichroism (CD)

Relative values of ORD and CD measurements, Advantages of CD over ORD

Instrumentation for measuring ORD and CD, Applications of ORD and CD

(v) Nuclear Magnetic Resonance (NMR) Spectroscopy

Nuclear Magnetic Resonance (NMR) Spectroscopy : Principle Basic Instrumentation of NMR Spectrometer

Applications of NMR Spectroscopy

(vi) Mass spectrometry

Mass spectrometry: Basic Principle Instrumentation and main components of mass spectrometers Ionization source, Mass analyzers, and Detectors **(LC-MS and GC-MS)**

Applications of Mass Spectrometry

UNIT – 3	**10 Hrs.**

Chromatography

Adsorption Chromatography: Simple Theory & Types

Operations of columns : Terminologies and concept

Elution : Types of elution methods

Supports : Concept of mesh size and mesh screen

Gas Chromatography: Principle, Basic set up of Gas chromatography system, Detectors and Uses of Gas chromatography

Gel Chromatography (molecular-sieve chromatography): Simple Theory, Materials (dextran, agarose and polyacrylamide gels), Advantages of gel chromatography, Estimation of molecular

weight and applications of gel chromatography

Ion-Exchange Chromatography: Principle, Properties of Ion Exchangers, Choice of Ion Exchangers, Technique and application of Ion Exchange chromatography.

High-Performance of Liquid Chromatography (HPLC): Principle, Application of pressure in HPLC, Advantages and uses of HPLC.

Affinity Chromatography: Principle, Methods of Ligand immobilization (Cyanogen-bromide-activated agarose, Aminoethyl- and hydrazide-activated polyacrylamide), uses of affinity chromatography

UNIT – 4	**10 Hrs.**

Electrophoresis

Iso-electric focusing (IEF): Principle, Technique and application, 2-D PAGE: Steps involved in 2-D PAGE, application in proteomics

Pulse-field gel electrophoresis: Principle, Technique and Application

Capillary electrophoresis: Principle, Technique and Application

X-ray crystallography

Interaction of X-ray with matter: Absorption, Scattering and diffraction (Bragg' s Law)

Preparation of crystals : Hanging and sitting drop vapor diffusion methods

X-ray diffraction methods

Application of X-ray Diffraction in Crystal structure

REFERENCES

1. Fundamentals of Bioanalytical Techniques And Instrumentation, Ghosal, Sabari, Avasthi, Anupama Sharma, Second Edition, Phi Learning Pvt. Ltd., 2018.
2. Bioanalytical Techniques, Abhilasha Shourie, Shilpa S. Chapadgaonkar, The Energy and Resources Institute, 2015
3. Biomolecular and Bioanalytical Techniques: Theory, Methodology and Applications, Vasudevan Ramesh, John Wiley & Sons Ltd, 2019
4. Handbook of Analytical Techniques, Helmut Günzler, Alex Williams, WILEY, 2001
5. Analytical Techniques in Biotechnology, Suzy Hill, Syrawood Publishing House, 2016
6. Analytical Techniques In Biotechnology, Goutam Bhowmik, Tata McGraw Hill Education Private Limited, 2010
7. Instrumental Methods of Chemical Analysis, G. R. Chatwal and A. K. Sham, 5th edition Himalaya Publishing House, 2005.
8. Instrumental Analysis, D. A. Skoog, F. J. Holler, S. R. Crouch, 11th edition, Brooks/Cole, a part of Cengage Learning, 2012.

COURSE OUTCOMES

After completion of the course student will be able to

1. Understand the basic concepts and principles of the major analytical techniques including instrumentation, sample preparation and standardization.
2. Evaluate the proper application of various analytical techniques for problem solving in biological sciences.
3. Demonstrate the ability to plan and execute experiments, and analyze and interpret the outcomes.
4. Design an analytical regimen to obtain data relevant to their research problem

Course Outcomes	Programme Outcomes												Programme Specific Outcomes		
	1	2	3	4	5	6	7	8	9	10	11	12	PSO1	PSO2	PSO3
CO 1	3	3	3									2	2	1	
CO 2	2	3	3									2	2	1	
CO 3	3	3	3									1	2	1	
CO 4	3	3	3									1	2	1	

UBT827E	PHARMACEUTICAL BT	Credits: 3
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week: 03		SEE Marks: 50

UNIT-I	10 Hrs.
Introduction: Introduction to pharmaceutical biotechnology, Pharmaceutical Industry. Drug design, development and Economics, Fundamental principles and processes involved in preclinical and clinical development of a chemical or biological entity. Orphan drugs Provisions for and use of unlicensed medicines, Drug abuse and dependence, Prescription and Non-prescription drugs. Regulations & guidelines for pharma ,CDSCO, fda, ichq7, usfdA21 cfr part11. **Drug metabolism:** Evolution of Drug Metabolism as a Science, Phase I Metabolism (microsomal oxidation, hydroxylation, dealkylation) Phase II Metabolism (Drug conjugation pathway) . Pharmacodynamics and Pharmacokinetics of drugs.	
UNIT–II	**10 Hrs.**
Toxicology: Basic concepts in toxicology, the mechanism of toxin action, biotransformation of toxins, their inactivation and removal from the body, Reactive intermediates. **Manufacturing principles and formulations:** Definitions, applications, composition, preparation, physicochemical considerations,. Preformulation Testing, Tablets, compressed tablets, tablet granulation, Coatings, Pills, Parental preparations, herbal extracts, Oral liquids, Ointments, short study of current biotech products, herbal medicines. Quality control, storage and stability of biotech products.	
UNIT–III	**10 Hrs.**
Stem cells in health care: Introduction to Stem Cell Biology, Fate Mapping of Stem Cells, Mesenchymal Stem Cells, Stem Cells and Neurogenesis and its application , Epidermal Stem Cells, Liver Stem Cells, Pancreatic Stem Cells, Stem Cells in the Epithelium of the Small Intestine and Colon. Application of epidermal stem cell in Tissue engineering, Hematopoietic Stem Cells, Classification and clinical manifestations of hematopoietic stem cell disorders.	

Drug delivery system:
Advanced Sustained Release Drug Delivery System, Advanced drug Delivery Systems, Liposomes and Nanoparticles Drug Delivery System, Biodegradable Drug Delivery System, Hydrogel based Drug Delivery System.

UNIT–IV	10 Hrs.

Analysis of biologicals & pharmaceuticals:
Vitamins Cold remedies Laxatives Analgesics, NSAIO, External antiseptics, Antacids, Antibiotics, Biologicals, Herbal products. Packaging techniques – Glass containers, plastic containers, film wrapper, bottle seals.

Advanced pharmacology:
Introduction to pharmaceutical chemistry, classification of drugs based on therapeutic actions using suitable examples. Antineoplastic agents, Immunomodulators, Heavy metals and heavy metal antagonists, Therapeutic gases. Free radical biology and antioxidants.

REFERENCE BOOKS *

1. Gary Walsh, (2013),Biopharmaceuticals Biochemistry and Biotechnology (2nd Edition), Wiley Publishers.
2. Bartram Katzung, (2009),Basic & Clinical Pharmacology(9th Edition), McGrawHill.
3. Leon Lachman, Herbert. Lieberman & Joseph Kanig, Vergese, (1987) The Theory & Practice of Industrial Pharmacy, (3 rd Edition) Publishing House Bombay.

COURSE OUTCOMES**

After completion of the course student will be able to

1. Apply and classify various biological sources of pharmaceutical products to retrieve the basic concept of pharmacology, drug metabolism .and their importance in biotechnology
2. Select and apply the toxicological studies of pharmaceutical products
3. Use knowledge of the techniques used in the manufacture of pharmaceutical products and apply in the field of Biopharmaceuticals.
4. Ability to discuss the concepts used in production of stem cells and analyse the applications and ethical issues of stem cells in the society.
5. Select and apply appropriate techniques advanced techniques in drug delivery system.
6. Demonstrate an ability to apply principles various other applications to protect the global community from various dreadful diseases.

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	-	2	2	2	3	3	1	-	-	-	-	-	3	2	1
CO2	-	3	3	3	3	2	3	-	-	-	-	-	2	2	1
CO3	-	2	3	2	3	1	-	-	-	-	-	-	3	2	-
CO4	-	2	3	2	3	1	-	-	-	-	-	-	2	2	-
CO5	-	3	3	2	3	1	-	-	-	-	-	-	2	3	-
CO6	-	3	3	3	3	2	2	-	-	-	-	-	2	2	3

UBT830E	CLINICAL RESEARCH	Credits: 03
L:T:P – 3:0:0		CIE Marks: 50
Total Hours/Week: 03		SEE Marks: 50

UNIT-I	10 Hours
Introduction The philosophy behind organization of research. Disease target identification and selection. Patenting new active substances. Receptor-based approaches, agonists, antagonists, enzyme inhibitors. Lead optimization and candidate selection of molecules for exploratory human investigation. In vitro and In vivo testing of new compounds Relationship between animal and human pharmacology. **Clinical pharmacology** Pre-clinical development to support testing in humans. Safety testing, Pharmaceutical development -formulations, manufacture and supply of materials, labeling and presentation, stability and storage, purity, compatibility, disposal; Concepts of Pharmacovigilance.	
UNIT–II	**10 Hrs.**
Therapeutics Clinical importance of Therapeutic Proteins, Antibodies, Enzymes; Hormones and Growth Factors, Interferon's, Interleukins and Additional Regulatory Factors. **Management of drugs** Management of common acute and chronic diseases. Major drug classes including biologicals. Measurement of drug effects Adverse drug reactions (short term & long term). Benefit and risk, Drug interactions; Prescribing for particular populations . Controlled drugs and drug dependence, Over dosage and treatment of poisoning. Patient compliance and information, Therapeutic Drug Monitoring.	
UNIT–III	**10 Hrs.**
Healthcare marketplace National and local formularies. Product information (Generic v/s Rx), advertising and claims Product support and promotion Product life-cycle management Product liability Codes of practice including the MHRA Blue Principles of health economics Pharmacoepidemiology Competition, in-licensing, co-marketing. **Social, ethical issues** patents and copyrights. Social-genetic discrimination: insurance and employment, human cloning, foeticide, sex determination. Ethical: somatic and germ line gene therapy, clinical trials, the right to information, ethics committee function. Preservation and clinical use of blood and blood components.	

UNIT–IV	10 Hrs.

Clinical research

Types of Epidemiology study designs, ecological (correlation) studies, Case reports and case series, prevalence surveys or cross-sectional studies, case control studies, Clinical Trials, Small Clinical Trials, Placebo Responses in Clinical Trials, Large Clinical Trials and Registries – Clinical Research Institutes, Data **Management in Clinical Research:** General Principles and Guide to Sources, Clinical Research from Pharmaceutical Industry Perspective.

REFERENCE BOOKS *

1. Gary Walsh., Biochemistry and Biotechnology, 2002, John Wiley & Sons Ltd.
2. Gallin and . J. I. Ognibene F. P, 2007 Principles and Practice of Clinical Research by, 2nd Edition, Elsevier Publication. ,
3. William J. Williams, Ernest Beutler, Allan JU. Erslev, Marshall A. Lichtman,2005, Hematology,
4. John Wiley & Sons Ltd by Arunabha Ray & Kavitha Gulati, 2007,Current Trends in Pharmacology IK Intl.

COURSE OUTCOMES**

1. Exploit the knowledge to know the clinical importance of different therapeutic products
2. An integrated understanding of the formulations, manufacturing and supply of materials
3. Ability to study the philosophy behind organization of research Ability to understand control measures uised in drug and its control
4. Ability to elucidate the marketing strategies of pharma products
5. Ability to compare the social and ethical issues
6. Ability to inculcate the epidemiology study designs, case reports and case series

*** Books to be listed as per the format with decreasing level of coverage of syllabus**

**** Each CO to be written with proper action word and should be assessable and quantifiable**

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	1	3	3	-	2	-	2	1	-	-	-	2	2	2	1
CO2	1	2	3	-	1	-	2	1	-	-	-	3	3	1	1
CO3	1	2	3	-	2	-	2		-	-	-	3	2	2	1
CO4	1	3	3	-	1	-	1	1	-	-	-	2	2	1	1
CO5	1	3	3	-	-	-	-	-	-	-	-	1	2	3	
CO6	1	3	3	-	1	-	2	-	-	-	-	3	3	3	3

UBT832E	HEALTH DIAGNOSTICS	Credits: 03
L:T:P – 3:0:0		CIE Marks: 50
Total Hours/Week: 03		SEE Marks: 50

UNIT-I	10 Hours

INTRODUCTION:

Biochemical disorders, Immune disorders, Infectious diseases, Parasitic diseases, Genetic disorders chromosomal disorders, single cell disorders and complex traits. Chromosomal disorders : autosomal; sex chromosomal; karyotype analysis.

DNA BASED DIAGNOSTICS

G-banding, in *situ* hybridization (FISH and on-FISH), and comparative genomic, hybridization (CGH). Cancer cytogenetics: spectral karyotyping. DNA diagnostics: PCR based diagnostics; ligation chain reaction, Southern blot diagnostics, array-based diagnostics, Genome sequencing and Metagenomics, DNA sequencing, genetic profiling, single nucleotide polymorphism. Haemoglobinopathies. Neuro developmental disorders. Neuro degenerative disorders. Dynamic mutations. G-banded chromosomal preparations for detection of autosomes of autosomal/sex chromosomal disorders. (translocation, deletion, Down's syndrome, Klumefelter syndrome, Turner's syndrome, etc.) FISH for detections of: translocations, inversions (using appropriate probes) (e.g., chro 9-22 translocation; X-Y translocation).

UNIT–II	10 Hrs.

Biochemical diagnostics

Inborn errors of metabolism, haemoglobinopathies, mucopolysaccharidoses, lipidoses, lipid profiles, HDL, LDL, Glycogen storage disorders, amyloidosis

Cell based diagnostics

Antibody markers, CD Markers, FACS, HLA typing, Bioassays

UNIT–III	10 Hrs.

Immunodiagnostics

Introduction, Antigen-Antibody Reactions, Conjugation Techniques, Antibody Production, Enzymes and Signal Amplification Systems, Separation and Solid-Phase Systems, Case studies related to bacterial, viral and parasitic infections. Diagnosis of infectious diseases, respiratory diseases (influenza, etc.) Viral diseases-HIV etc., bacterial diseases, enteric diseases, parasitic diseases and mycobacterium diseases. Phage display, immunoarrays, FACs.

UNIT–IV	10 Hrs.

Imaging diagnostics

Imaging Techniques (Basic Concepts), Invasive and Non-Invasive, Electrocardiography (ECG), Uses of ECG, Electroencephalography (EEG), Use of EEG, Computerized Tomography (CT), Uses of CT, Magnetic Resonance Imaging (MRI), uses of MRI, Ultrasound Imaging (US), Uses of Ultrasound, Planning and Organization of Imaging Services in Hospital, Introduction, Planning, Physical Facilities, Layout, Organization, Organization and Staffing, Records, Policies, Radiation Protection.

REFERENCE BOOKS *

1. Lisa Anne Shimeld.,2000 Essentials of Diagnostic Microbiology
2. Balley & Scott's. 1998 Diagnostic Microbiology, 2ND edition,
3. Burtis & Ashwood,.Tietz ,2005,Text book of Clinical Biochemistry.

COURSE OUTCOMES**

1. Ability to study Biochemical disorders, chromosomal disorders.
2. Able to study DNA based diagnostics.
3. Analyse Biochemical diagnostics.
4. Understand cell based diagnostics.
5. Analyse Immunodiagnostics
6. Understand imaging diagnostics

Course Outcomes	Programme Outcomes (POs)												Program Specific Outcomes (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	2	2	2	-		2	-	-	-	-	-	-	1	1	1
CO2	2	2	2	-	2	3	-	-	-	-	-	-	2	1	2
CO3	3	3	2	-	2	2	-	-	-	-	-	1	1	1	2
CO4	3	3	3	-	2	3	-	-	-	-	-	1	2	1	3
CO5	1	3	3	-	-	-	-	-	-	-	-	1	2	3	
CO6	1	3	3	-	1	-	2	-	-	-	-	3	3	3	3

UBT833E	VALIDATION & QUALITY CONTROL	Credits: 3
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week: 03		SEE Marks: 50

UNIT-I	10 Hrs.

Introduction

Validation and Regulatory Affairs in Bio (Pharmaceutical) Manufacturing: An Introduction to FDA Operations & Industry Compliance Regulations, The Fundamentals of Regulatory Compliance with respect to Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) & Good Laboratory Practice (GLP). An Introduction to the Basic Concepts of Process Validation & Qualification (IQ, OQ & PQ) Procedures, A Review of Prospective, Concurrent, Retrospective Validation & Revalidation . Validation of Water, Active Pharmaceutical Ingredients (APIs) & Aseptic Processes. Validation of Non- Sterile Processes (used in the manufacture of Solids, Liquids, & Semisolid Dosage Forms). FDA and ICH guidelines .

UNIT–II	10Hrs.

Medical Device, In-Vitro Diagnostics & Packaging Validation Issues, Validation of Analytical Methods, Computerized & Automated Systems under 21 CFR Part 11.

Standards

Introduction, ISO 9000 Series of Standards, Management Responsibility, Quality System, Contract Review, Design Control, Document and Data Control, Preservation and Delivery, Control of Quality Records, Internal Quality Audits, Training, Servicing, Statistical Techniques, ISO-9001-2000, Scope, Normative Reference, Terms and Definitions, Quality Management, System, Documents Requirements, Management's Responsibility, Resource Management, Infrastructure, Product Realization, Measurement, Analysis and Improvement, ISO-14001 - Environmental Management Systems.

UNIT–III	10 Hrs.

Implementation

The Influence of Good Automated Manufacturing Practice (GAMP); The FDA's Approach to GMP Inspections of Pharmaceutical Companies.

Quality System, Contract Review, Design Control, Document and Data Control, Purchasing,Control of Customer Supplied Product, Product Identification and Traceability, Process Control, Inspection and Testing, Final Inspection and Testing, Control of Inspection, Measuring and Test Equipment, Inspection and Test Status, Control of Nonconforming Product, Corrective and Preventive Action, Handling, Storage, Packaging, Preservation and Delivery, Control of Quality Records, Internal Quality Audits, Training, Servicing, Statistical Techniques.

Quality Objectives, Quality Planning, Quality Control, Quality Assurance, Quality Improvement

UNIT–IV	10 Hrs.

Quality

Terminology Relating to Quality, Quality Requirement, Customer Satisfaction, Capability; Terms Relating to Management, Management System, Quality Management System, Quality Policy, Continual Improvement, Effectiveness, Efficiency; Relating to Process and Product, Process, Product, Procedure; Terms relating to Characteristics, Quality Characteristics; Terms Relating to Conformity, Non-Conformity, Defect, Preventive Action, Corrective Action, Correction, Rework, Regrade, Repair, Scrap, Concession, Deviation Permit, Release; Terms Relating to Documentation, Information, Document, Specification, Quality Manual, Quality Plan, Record; Terms Relating of

Examination, Objective Evidence, Inspection, Test. Metrological Confirmation.

REFERENCE BOOKS*

1. Pharmaceutical Process Validation, 3rd Edition, Edited by Robert Nash and Alfred Wachter, Marcel Dekker, 2003
2. Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control From Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed., 2000, 723 pp.,
3. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed., 1998.
4. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance
5. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. . Cloud,Interpharm Press, 1998.
6. Commissioning and Qualification, ISPE Pharmaceutical Engineering Baseline Guides Series, 2001.

COURSE OUTCOMES**

1. Ability to comprehend the validation techniques, process, concepts.
2. Ability to analyse the good practices in lab, clinical and manufacturing practices
3. Ability to retrieve the regulations , fundamentals of validations and its procedures
4. Capable of understanding the ISO standards and environmental management systems
5. An ability to analyse the analytical methods of validation, issues and automated system and standards
6. Ability to interpret guidelines and discuss the case studies
7. Ability to discuss the quality control measures used in industries
8. Ability to analyse the Quality Management System

Course Outcomes	Programme Outcomes												Programme Specific Outcomes		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**PSO1**	**PSO2**	**PSO3**
CO 1	2					2	3	1						1	3
CO 2	2			2		3	3	3					2	2	3
CO 3	3					3	2	2				3	2	3	2
CO 4	2					3	1	3				3	2	3	3
CO 5	2					2	3	3				2	2	2	3
CO 6	2			2		2	1	2				2	2	3	2
CO 7	2			1		3	1	2				1	2	3	2
CO8	2			2		3	1	2				3	3	2	2

UBT834E	PRODUCT DEVELOPMENT	Credits: 3
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week: 03		SEE Marks: 50

UNIT-I	12 Hrs.

Essentials of product development

The product development process, privacy policies and *K*nowledge of basic laboratory procedures, Standard Operating Procedure (SOPs), process flows in manufacturing, product life cycle and competitor studies. Stability studies – Stability Testing of new Drug Substances and Products –types and stages of testing, Stress Testing, storage conditions. Manufacturing Process for Recombinant pharma Products. Production of pharmaceuticals by genetically engineered cells- hormones and vaccines. Approved Biotech Drugs.

UNIT–II	12Hrs.

Interpersonal Skills

Understand work output requirements, company policies, delivery of quality work on time and report any anticipated reasons for the delay, effective interpersonal communication, conflict-resolution techniques, importance of collaborative working, multi-tasking, training the team members, knowledge of project management.

UNIT–III	10 Hrs.

Reporting and formulations

Reporting – power point presentations, technical writing, Principal investigator, communication with upstream and downstream teams.Problem Solving and Decision Making. Types of adverse drug reactions (ADR) and their treatment. Activity screening, formulations of energy drinks, bars, sports drinks, fortified products, geriatric products, veterinary products, immune boosters

UNIT–IV	10 Hrs.

Safety and Security at workplace

Different types of occupational health hazards, knowledge of chemical substances -characteristics & safety measures. Use of safety gears, masks, gloves and accessories, evacuation procedures for workers and visitors. Health, safety and security issues – types (illness, fire accidents). Classification of dangerous materials with pictorial symbols, Safety in transportation of dangerous materials by road, rail, ships and pipelines. Safety in bulk storage of hazardous substances.

REFERENCE BOOKS*

1. Endrenyi, L., Declerck, D. and Chow, S. (2017). Biosimilar Drug Product Development. Boca Raton: CRC Press.
2. Jain, N. (2011). Pharmaceutical product development. New Delhi: CBS Publishers

COURSE OUTCOMES**

1. Understand analyze and apply the techniques and essentials of product development.
2. Ability to understand the various techniques in Pharma industries.
3. Demonstrate the different interpersonal skills.
4. Demonstrate the methodologies and applications of Project development and management.
5. Ability to comprehend various techniques involved in Reporting.
6. Describe the different formulations of various energy drinks

7. Analyse and list the various health hazards in industry.
8. Ability to understand importance of safety and implement in various Industries.

Course Outcomes	**Programme Outcomes**												**Programme Specific Outcomes**		
	1	2	3	4	5	6	7	8	9	10	11	12	PSO1	PSO2	PSO3
CO 1		2	2	3	1			3	1		2	2	2	1	1
CO 2		2	2	3	3		2					3	2	1	
CO 3					2	3		2	3	3	3	3	2	1	1
CO 4		3	3	3	3	3	2	3	3	3	3	3	2	1	2
CO 5			3	3	3		2			2	2	3	2	1	
CO 6					2							3	2	1	
CO 7				2	3	3		3					2	1	
CO 8					2	3	3	3				2			

UBT835E	VALIDATION & QUALITY ASSURANCE	Credits: 2
L: T: P – 2-0-0		CIE Marks: 50
Total Hours/Week: 02		SEE Marks: 50

UNIT-I	7 Hrs.

Introduction

Validation and Regulatory Affairs in Bio (Pharmaceutical) Manufacturing: An Introduction to FDA Operations & Industry Compliance Regulations, The Fundamentals of Regulatory Compliance with respect to Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) & Good Laboratory Practice (GLP). An Introduction to the Basic Concepts of Process Validation & how it Differs from Qualification (IQ, OQ & PQ) Procedures, Validation life cycle, A Review of Prospective, Concurrent, Retrospective Validation & Revalidation . FDA and ICH guidelines.

UNIT–II	6 Hrs.

Types of Validation

Validation of Water & Thermal Systems, including HVAC Facilities & Cleaning Validation. Validation of Active Pharmaceutical Ingredients (APIs) Packaging Validation Issues, Validation of Analytical Methods, Computerized & Automated Systems under 21 CFR Part 11.

Standards

Introduction, ISO 9000 Series of Standards, Management Responsibility, Quality System, Contract Review, Design Control, Document and Data Control, Preservation and Delivery, Control of Quality Records, ISO-9001-2000, Scope, Normative Reference, Terms and Definitions, Quality Management, System, Documents Requirements, Management's Responsibility, Resource Management, Infrastructure, Product Realization, Measurement, Analysis and Improvement, ISO-14001 - Environmental Management Systems

UNIT–III	7 Hrs.

Quality Assurance

The Influence of Good Automated Manufacturing Practice (GAMP),Quality System, Contract Review, Design Document and Data Control, Purchasing, Control of Customer Supplied Product, Process Control, Corrective and Preventive Action, Handling, Storage, Packaging, Preservation and Delivery, Control of Quality Records, Internal Quality Audits, Quality Objectives, Quality Planning, Quality Control, Quality Assurance, Quality Improvement.

UNIT–IV	6 Hrs.

Quality Control

Efficiency; Relating to Process and Product, Process characteristics, Quality Characteristics, Documentation, Information, Specification, Quality Manual, Quality Plan, Record of Examination, Objective, Inspection.Quality Requirement, Customer Satisfaction, Capability; Management System, Quality Management System, Quality Policy, Continual Improvement.

REFERENCE BOOKS*

1. Pharmaceutical Process Validation, 3rd Edition, Edited by Robert Nash and Alfred Wachter, Marcel Dekker, 2003
2. Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control From Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed., 2000, 723 pp.
3. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed., 1998.
4. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance
5. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press, 1998.
6. Commissioning and Qualification, ISPE Pharmaceutical Engineering Baseline Guides Series, 2001.

COURSE OUTCOMES**

1. Ability to comprehend the validation techniques, process, concepts.
2. Ability to analyse the good practices in lab, clinical and manufacturing practices
3. Capable of understanding the ISO standards and environmental management systems
4. Ability to analyse the analytical methods of validation, issues and automated system and standards
5. Ability to discuss the quality control measures used in industries
6. Ability to analyse the Quality Management System

Course Outcomes	Programme Outcomes												Programme Specific Outcomes		
	1	2	3	4	5	6	7	8	9	10	11	12	PSO1	PSO2	PSO3
CO 1	2				2	2								1	3
CO 2	2	3	1	2	3	3							2	2	3
CO 3	3	2			3	3						3	2	3	2
CO 4	2	2	1		3	3	1					3	2	3	3
CO 5	2	1			2	2	3					2	2	2	3
CO 6	2		1	2	2	2	1					2	2	3	2