BVVS

BASAVESHWAR ENGINEERING COLLEGE (AUTONOMOUS), BAGALKOT

DEPARTMENT OF BIOTECHNOLOGY

B.E. VII SEMESTER

2021-22

Sl. No.	Subject Code	Subject Title	Hours/Week					Exam Marks		
			Credits	Lecture	Tutorial	Practical	Total	CIE	SEE	Total
1	UBT704C	Economics & Plant Design	3	2	2	0	4	50	50	100
2	UBT716H	Industrial Management & Entrepreneurship	3	3	0	0	3	50	50	100
3	UBT715C	Downstream Processing Technology	3	2	2	0	4	50	50	100
4	UBT72XE	Elective – 4	3	3	0	0	3	50	50	100
5	UBT73XE	Elective – 5	3	3	0	0	3	50	50	100
6	UXX70XN	Open elective -3	3	3	0	0	3	50	50	100
7	UBT710L	Bioseparation Techniques Lab	1	0	0	2	2	50	50	100
8	UBT717L	Food Analysis Techniques Lab	1	0	0	2	2	50	50	100
9	UBT701T	Technical seminar	1	0	2	0	2	50	50	100
10	UBT711I	Industrial Internship	2	0	0	4	4	50	50	100
Total			**23**	**16**	**6**	**08**	**30**	**500**	**500**	**1000**

Elective - 4	**Elective - 5**
UBT722E: Aquaculture & Marine biotechnology	UBT731E: Nanobiotechnology & Biomaterials
UBT723E: Dairy Biotechnology	UBT732E: Computational biology
UBT724E: Food processing Technology	UBT733E: Bioconjugative technology
UBT725E: Protein Engineering & Drug Design	UBT734E: Food biotechnology

UBT 704C: Economics and Plant Design
3 Credits (3-0-0)

UNIT 1

Process design development **10 Hours**

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 2

Capital investments **10 Hours**

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 3

Cost analysis **10 Hours**

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

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

UNIT 4

Profitability Analysis **10 Hours**

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

Total: 40 hours

Text Books

1. Peters and Timmerhaus, Plant Design and Economics for Chemical Engineers, 5th Edition, McGraw Hill. 2017
2. Rudd and Watson (1987) Strategy of Process Engineering, Wiley.
3. Poornima M C, “Entrepreneurship Development and Small Business Enterprises”, Pearson education,2006

Reference Books

1. Vasanth Desai,”Dynamics of Entrepreneurial Development & Management”, Himalaya Publishing House.4th Edition,2007.
2. Khanka SS ,” Entrepreneurship Development, S Chand & Co.Revised edition,2007.
3. Thomas W. Zimmer, Norman M. Scarborough, Essentials of Entrepreneurship and small Business Management, Pearson education,5th Edition,2008.

Course Outcomes

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.

UBT716H: Industrial Management and Entrepreneurship
3 Credits (3-0-0)

UNIT 1

Development of management thoughts and its functions **10 Hours**

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 2

Quantitative techniques in managerial decisions **10 Hours**

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 3

Production And Material Management **10 Hours**

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 4

Entrepreneurship& personnel management **10 Hours**

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.

Total: 40 hours

Text Books

1. O.P. Khanna - "Industrial Engineering & Management", Dhanpat Rai & Sons, 1992.

Reference Books

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

Course Outcomes

1 Ability to recall and recollect the history theories and definition of management and its importance in society
2 To analyze and apply the basic concepts of Quantitative techniques of management
3 Ability to know the difference between production and productivity, measurement and cost analysis
4 Explore the knowledge of production costs, planning and material management
5 Able to make basic economic analysis of project
6 Ability to understand the role and importance of entrepreneurship in economic development

UBT715C: Downstream processing technology
3 Credits (2-2-0 hrs)

UNIT 1

Introduction: **10 Hours**

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 2

Primary Recovery Operations **L- 10 Hours**

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 3

Chromatography **L-10 Hours**

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 4

Electrophoresis **L- 10 Hours**

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.

Total: 40 hours

Text Books

1. Bioseparations-Principles and techniques, by B.Sivasankar, Kindle edition,PHI Publishers,1st Edition, 2009.
2. Biophysical chemistry principles and Technques by Upadhay and Nath,Himalaya Publishing House, 3rd edition, 2010

Reference Books

1. NPTEL Source material
2. Bioseparations - Downstream processing for biotechnology by Belter P.A., Cussier E. and Wei Shan Hu., Wiley Interscience Pub, 1988.
3. Separation Processes in Biotechnology by Asenjo J. and Dekker M, Taylor & Francis,2008.
4. Product Recovery in Bioprocess Technology – biotol Series, VCH, 1992.
5. Rate controlled separations by Wankat P.c., Elsevier, 1990

Course Outcomes

1 Analyse the role and importance of downstream processing and cell disruption techniques.
2 Ability to comprehend and analyse the extraction and precipitation techniques.
3 Identify and analyse the application of different membranes used in purification.
4 Ability to analyse the basic principles and applications of Chromatography.
5 Analyse and apply the electrophoretic techniques in seperation of biomolecules.
6 Ability to understand the downstream processing Technology using unit operations

UBT722E: Aqua culture & Marine Biotechnology
3 Credits (3-0-0)

UNIT 1

Aquatic environment **10 Hours**

Major physical and chemical factors (light, temperature, gases, nutrients). Aquatic biota: phytoplankton, zooplankton, benthos, periphyton, macrophytes, fish and other animals. Production & Nutrient dynamics in lakes, rivers, estuaries and wetlands. Eutrophication and water pollution: monitoring and control conservation and management of lakes, rivers and wetlands. Importance of coastal aquaculture- Design and construction of aqua farms, Criteria for selecting cultivable species. Culture systems – extensive, semi intensive and intensive culture practices

Aqua culture

Classification and Characteristics of Arthropoda. Crustacean characteristic key to important species of Prawns and Shrimps, General biology, of – Shrimp and Prawn, Finfish, Marine and freshwater fish. Preparation, culture and utilization of live food organisms, phytoplankton, zooplankton cultures, quality evaluation of Cyst, hatching and utilization, culture and cyst production.

UNIT 2

Aquaculture engineering and techniques **10 Hours**

Principles and criteria for site selection; multi-design, layout plan for prawn, shrimp and fish hatchery; design, lay-out plan and pond construction for grow- out production, design and construction of feed mill and installation of machineries. Chromosome manipulation in aquaculture - hybridization, ploidy induction, gynogenesis, androgenesis and sex reversal in commercially important fishes. Application of microbial biotechnology in culture ponds, bioaugmentation, bioremediation, nutrient cycling, and biofertilization.Probiotics – imunostimulants. Tools for disease diagnosis in cultivable organisms Enzyme immuno assays - Dot immunobinding assay - Western blotting - Latex agglutination test - Monoclonal antibodies - DNA based diagnosis. Cryopreservation techniques.

UNIT 3

Marine environment **10 Hours**

Biological Oceanography: The division of the marine environment – benthing, pelagic, batuyal, littoral. Ocean waters as biological environment. Distribution and population of plants and animals. Marine ecology and fisheries potential. Effects of pollution on marine life. Geological and geophysical Oceanography: geophysical and geological processes. Ocean basin rocks and sediments.

Marine microbiology

Biology of micro-organisms used in genetic engineering *(Escherichia coil, Rhizobium sp., Agrobacterium tumefaciens, Saccharomyces cerevisiae, phage lambda, Nostoc, Spirulina, Aspergillus, Pencillium and Streptomyces).* Methods of studying the marine micro-organisms collection, enumeration, isolation, culture & identification based on morphological, physiological and biochemical characteristics. Preservation of marine microbes, culture collection centre (ATCC, IMTECH, etc.). Microbial nutrition and nitrogen fixation.Seafood microbiology - fish & human pathogens. Indicator of Pollution - faecai coliforms - Prevention &control.

UNIT 4

Marine biotechnology and pharmacology **10 Hours**

Physical, Chemical and Biological aspects of marine life. Air – Sea interaction – Green house gases (CO2 and Methane). Marine pollution-major pollutants (heavy metal, pesticide, oil, thermal, radioactive, plastics, litter and microbial). Biological indicators and accumulators: Protein as biomarkers, Biosensors and biochips. Biodegradation and Bioremediation. Separation, purification and bioremoval of pollutants. Biofouling - Biofilm formation, Antifouling and Anti boring treatments. Corrosion Process and control of marine structures. Biosafety – special characteristics of marine environment that bear on biosafety. Ethical and moral issues - food health, and environmental safety concerns. Medicinal compounds from marine flora and fauna - marine toxins –antiviral, antimicrobial. Extraction of crude drugs, screening, isolation, purification and structural

characterization of bioactive compounds.

Total: 40 hours

Text Books

1. Kirchman, D.L,. Microbial ecology of the oceans. Wiley – liss, New York, 542 pp,2005
2. Kenneth, C. Hingham and Leonard Hill, 1969. The comparative endocrinology of the invertebrates. Edward Arnold Ltd

Reference Books

1. Farming the edge of the sea. Fishing News Ltd. London.
2. Finger man, M.. Recent advances in Marine Biotechnology. Vol. 4,2000
3. Kenneth, B.D., 2000. Environmental impacts of Aquaculture. CRC. pp. 214 ,2000

UBT723E: Dairy Biotechnology
3 Credits (3-0-0)

UNIT 1

Dairy Industry and Microbiology **10 Hours**

Overview of dairy industry, Characteristics of dairy Industry. Manufacturing & processing of dairy products, effect of processing on constituents and methods of evaluation of dairy products. Morphological and biochemical characteristics of important groups of milk microbes and their classification i.e.psychrotrophs, mesophiles, thermodurics, and thermophiles. Impact of various stages like milking, chilling, storage and transportation on microbial quality of milk, Direct and indirect rapid technique for assessment of microbial quality of milk. Food infection, intoxication and toxic infection caused by milk borne pathogens. Microbiological changes in bulk refrigerated raw milk; Mastitis milk: organisms causing mastitis, detection of somatic cell count (SCC). Role of microorganisms in spoilage of milk Significance of antimicrobial substances naturally present in milk (responsible for its nutraceutical properties): immunoglobulin, lactoferin, Lysozymes

UNIT 2

Dairy biotechnology **10 Hours**

Genetic engineering of bacteria and animals intended for dairy-based products: DNA cloning. protoplast fusion & cell culture methods for trait improvement with instances cited. Enzymes in dairy industry & production by whole cell immobilization. Biotechnology of dairy effluent treatment. Ethical issues relating to genetic modification of dairy microbes & milk-yielding animals.

Dairy engineering

Sanitization: Materials and sanitary features of the dairy equipment. Sanitary pipes and fittings, Description, working and maintenance of can washers, bottle washers. CIP cleaning and designing of system. Homogenization, Pasteurization, sterilization septic packaging and equipment. Filling Operation: Principles and working of different types of bottle filters and capping machine, pouch filling machine maintenance.

UNIT 3

Dairy process engineering **10 Hours**

Evaporation: Basic principles of evaporators, Different types of evaporators used in dairy industry, Drying: Introduction to principle of drying, Equilibrium moisture constant, bound and unbound moisture. Fluidization Mechanization and equipment used in manufacture of indigenous dairy products, Butter and Ghee making machine, Ice-cream and Cheese making equipments. Membrane Processing: Ultra filtration, Reverse Osmosis and electro dialysis in dairy processing, membrane construction & maintenance for electro-dialysis & ultra-filtration, Ultra filtration of milk, Effect of milk constituents on operation.

Dairy plant design and layout

Introduction of Dairy Plant design and layout. Type of dairies, perishable nature of milk, reception flexibility. Classification of dairy plants, selection of site for location. Dairy building planning, Process schedule, basis of dairy layout, General points of considerations for designing dairy plant, floor plant types of layouts, service accommodation, single or multilevel design.

UNIT 4

Quality and safety monitoring in dairy industry **10 Hours**

Current awareness on quality and safety of dairy foods; consumer awareness and their demands for safe foods; role of codex alimentations commission (CAC) in harmonization of international standards; quality (ISO 9001:2000) and food safety (HACCP) system National and international food regulatory standards; their role in the formulation of standards for controlling the quality and safety of dairy foods. Good Hygiene Practices (GHP): Rapid assessment of dairy food for microbial and non-microbial contaminants Quality of water and Quality of air & personnel hygiene.

By products technology

Status, availability and utilization of dairy by-products in India and abroad, associated economic and pollution problems. Physico-chemical characteristics of whey, butter milk and ghee residue, by-products from skim milk

such as Casein; Whey processing & utilization of products generated from whey.

Total: 40 hours

Text Books

1. Diary Science & Technology Handbook (Vols. 1-3). Ed by Hui, Y.H, Wiley Publishers,2007
2. Handbook of Farm, Dairy & Food Machinery - Myer Kutz- Andrew Publishers,2005

Reference Books

1. Diary Microbiology Handbook (3rd Ed). Robinson, R.K., Wiley Publishers,2001
2. Comprehensive Biotechnology (Vol. 6) Ed N.C Gautam- Shree Pblns,2002.
3. General Microbiology (Vol. 2) – Powar & Daginawala- Himalaya Publishers,2005
4. Milk composition, production & biotechnology (Biotechnology in Agriculture Series). CABI Publishers,2005

UBT724E: Food Processing Technology
3 Credits (3-0-0)

UNIT 1

Introduction **10 Hours**

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 2

Detection of Microorganisms **12 Hours**

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 3

Food Spoilage & Preservation **10 Hours**

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 4

Food Engineering **10 Hours**

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.

Total: 42 hours

Text Books

1. Food Science & Nutrition, by Sunetra Roady, Oxford University Press, 2007.
2. Food microbiology by William Frazier and Westhoff D.C, 4th edn,TATA McGraw Hill Pub (2005)

Reference Books

1. Modern Food Micro-Biology by James M.Jay, CBS Publishers. (2005)
2. Food Microbiology by K.Vijay Ramesh MJP Publishers(2007)
3. Plant biotechnology In Agriculture by K. Lindsey and M.G.K. Jones, Prentice Hall, USA. (1990),
4. Food Science By Potter N.N. and Joseph Hotchkiss, 5 th edn, CBS Pub,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

UBT725E: Protein Engineering and Drug Design

3 Credits (3-0-0)

UNIT 1

Structure of proteins **10 Hours**

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 2

Molecular modelling **10 Hours**

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 3

Insilico drug design **10 Hours**

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 4

Docking methods **10 Hours**

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.

Total: 40 hours

Text Books

1. Bioinformatics Methods & Applications: Genomics, Proteomics & Drug Discovery, S C Rastogi, Mendiratta & P Rastogi, PHI,4th Edition, 2013

Reference Books

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 methodsand computer - assisted drug discovery

UBT731E: Nanobiotechnology and Biomaterials

3 credits (3hrs)

UNIT 1

Introduction to Nanotechnology **10 Hours**

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 2

Biopolymers **10 Hours**

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 3

Synthetic polymers **10 Hours**

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 4

Biocompatibility **10 Hours**

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.

Total: 40 hours

Text Books

1. B.Vishwanath " Nano Materials" Published by Narosa Publishing House Pvt. Ltd., New Delhi, 2014.

Reference Books

1. K Eric Drexler "Unbounding The Future" Quill, 1993.
2. Mark Ratner And Daniel Ratner "Nanotechnology: A Gentle Introduction To Next Gig Idea" Pearson Education Ltd, 2003.
3. Veronique Migonney "Biomaterials" John Wiley 2014

Course Outcomes

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.

UBT732E: Computational Biology
3Credits (3-0-0)

UNIT 1

Introduction to computational biology and sequence analysis **10 Hours**

Molecular sequences, Genome sequencing: pipeline and data, Next generation sequencing data, Biological databases: Protein and Nucleotide databases, Sequence Alignment,Dynamic Programming for computing edit distance and string similarity, Local and Global Alignment, Needleman Wunsch Algorithm, Smith Waterman Algorithm, BLAST family of programs, FASTA algorithm, Functional Annotation, Progressive and Iterative Methods for Multiple sequence alignment, Applications.

UNIT 2

Phylogenetics **10 Hours**

Introduction to Phylogenetics, Distance and Character based methods for phylogenetic tree construction: UPGMA, Neighbour joining, Ultrametric and Min ultrametric trees, Parsimonous trees, Additive trees, Bootstrapping.

Protein structure, modelling and simulations

Protein Structure Basics, Visualization, Prediction of Secondary Structure and Tertiary Structure, Homology Modeling, Structural Genomics, Molecular Docking principles and applications, Molecular dynamics simulations.

UNIT 3

Machine learning, systems biology and other advanced topics **10 Hours**

Machine learning techniques: Artificial Neural Networks and Hidden Markov Models:Applications in Protein Secondary Structure Prediction and Gene Finding, Introduction toSystems Biology and its applications in whole cell modelling, Microarrays and Clusteringtechniques for microarray data analysis, informatics in Genomics and Proteomics, DNA computing.

UNIT 4

Perl for bioinformatics **10 Hours**

Variables, Data types, control flow constructs, Pattern Matching, String manipulation, arrays,lists and hashes, File handling, Programs to handle biological data and parse output files for interpretation

Laboratory Demonstrations for

Biological Databases, Sequence alignment: BLAST family of programs, FASTA, ClustalW for multiple sequence alignment, Phylogenetics software, Homology Modeling and Model evaluation, AutoDock, GROMACS, Prokaryotic and Eukaryotic Gene finding software, Programs in PERL.

Total: 40 hours

Text Books

1. David W. Mount Bioinformatics: Sequence and Genome Analysis, Cold Spring Harbor Laboratory Press, Second Edition, 2004.
2. Arthur M. Lesk, Introduction to Bioinformatics by Oxford University Press, 2008.

Reference Books

1. Baldi, P., Brunak, S. Bioinformatics: The Machine Learning Approach, 2nd ed., East West Press, 2003
2. Baxevanis A.D. and Oullette, B.F.F. A Practical Guide to the Analysis of Genes and Proteins, 2nd ed., John Wiley, 2002
3. Durbin, R. Eddy S., Krogh A., Mitchison G. Biological Sequence Analysis: Probabilistic
4. Models of Proteins and Nucleic Acids. Cambridge University Press, 1998.

UBT733E: Bioconjugative Technology
3 Credits (3-0-0)

UNIT 1

Bioconjugative technology **10 Hours**

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

UNIT 2

Chemistry of active groups **10 Hours**

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 3

Enzyme and nucleic acid modification and conjugation **10 Hours**

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 4

Bioconjugate applications **10 Hours**

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.

Total: 40 hours

Text Books

1. Bioconjugate Techniques, G.T. Hermanson, Academic Press, 2 nd edition 2008
2. Bioconjugate techniques , Greg T Hermanson, academic Press ,Global store , 2016

Reference Books

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

UBT734E: Food Biotechnology
3 Credits (3-0-0)

UNIT 1

Introduction **10 Hours**

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 2

Microbial biotechnology of food **10 Hours**

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 3

Plant food applications **10 Hours**

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 4

Transplastomic technology (chloroplast engineering) **12 Hours**

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.

Total: 42 hours

Text Book

1. Kalidas s, Gopinadhan P, Anthony P and Robert E.Levin- " Food Biotechnology"- second edition, CRC press, 2006

Reference Books

1. Gustavo F.G and Gustavo V.B,-" Food Science and Food Biotechnology"- CRC press, 2003
2. Mahesh S.-" Plant Molecular Biotechnology"- first edition, New age international publishers,

, 2008
3. 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

UBT 717L: Food Analysis Techniques Lab
1 Credit (0-0-2)

1. Proximate analysis of foods
2. Nutritional profiling of food samples for labelling (Carbohydrates, protein and fat)
3. Nutritional profiling of food samples for labelling (Vitamins and minerals)
4. Determination of calories in foods.
5. Determination of viscosity and texture of food sample
6. Detection of microbial load in processed food a sample
7. Extraction and detection of active ingredients in foods
8. Extraction of chitin, chitosan and glucosamine from prawn shells/mushrooms
9. Detection of Antioxidant property of Nutraceuticals
10. Sensory evaluation
11. Visit to NABL lab

Reference Books:

1. Food analyses by S Suzanne Nielsen, Fourth edition, Springer publisher, 2010
2. Food Regulation: Law, Science, Policy and Practice, N.D. Fortin, Wiley Publication, 2nd Edition, 2016
3. A Practical Guide to Food Laws and Regulations. Kiron Prabhakar, Bloomsbury Professional India, 1st Edition, 2016
4. Food Safety and Standards Act and Regulations, Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, Government of India, 2006

Course outcomes:

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

1. Analyze different food samples for quality.
2. Evaluate food samples for quality.
3. Evaluate food samples for chemical and microbial safety.
4. Analyze the data for the acceptability of food sample

QUESTION PAPER PATTERN OF CIE (Continuous Internal Evaluation):

1. CIE comprises of 3 tests, each of 30 marks and I hr duration, totaling to 90 marks and later is scaled down to 45 mark
2. Each CIE will be covering one and half unit
3. Any two full questions to be answered out of three questions and each question carries fifteen marks
4. Assignment: quiz/ objective tests etc carries five mark

QUESTION PAPER PATTERN of SEE:

1. Total of Eight Questions with Two from each unit to be set uniformly covering the entire syllabus.
2. Each question should not have more than four sub questions.
3. Any Five Full questions are to answered choosing at least one from each unit.

Laboratory Assessment:

1) Each laboratory subject is evaluated for 100 marks (50 CIE and 50 SEE)

2) Allocation of 50 marks for CIE

- Performance and Journal write-up: marks for each experiment = 30 marks/No. of proposed experiments.
- One practical test, for 20 marks (5 write-up, 10 conduction, calculation, Result etc., 5 –viva-voce)

3) Allocation of 50 marks for SEE

Major and Minor	: 35 marks (Write-up 25%, conduction 50%, calculation and results 25%)
Spotting	: 08 marks
Viva-Voce	: 07 marks

B.E. VIII SEMESTER

2021-22

Sl. No.	Subject Code	Subject Title	Hours/Week					Exam Marks		
			Credits	Lecture	Tutorial	Practical	Total	CIE	SEE	Total
1	UBT82XE	Elective – 6 (Online)	03	3	0	0	3	50	50	100
2	UBT83XE	Elective – 7 (Online)	03	3	0	0	3	50	50	100
3	UBT806P	Project work	15	0	0	30	30	50	50	100
		Total	**21**	**6**	**0**	**30**	**36**	**30**	**35**	**300**

Electives - 6

UBT823E: Chemical Plant utilities & Safety
UBT824E: Metabolic Engineering
UBT825E: Industrial Waste Water Treatment
UBT827E : Pharmaceutical BT

Electives - 7

UBT830E: Clinical Research
UBT832E: Health Diagnostics
UBT833E: Validation & Quality Control
UBT834E: Product Development

UBT823E: Chemical Plant Utilities and Safety
3 Credits (3-0-0)

UNIT 1

Introduction: **10 Hours**

Different utilities. Role of utilities in process plant operations and criteria for selection and estimation of suitable utilities. Water: Water resources. Process water, Cooling water, drinking water and boiler feed water Quality Standards. Water treatment processes for drinking, process and boiler feed. Storage and handling of water. Types and selection of pumps, piping and accessories. Water pre treatment.

Air:

Compressed air, blower air, fan air. Types of compressor and vacuum pumps and selection. Power requirements, performance and related calculations. Booster and receivers. Quality of compressed air for instruments and processes. Compressed air distribution system-piping and accessories. Air-water vapour system: humidification/ dehumidification and evaporative cooling-related calculations.

UNIT 2

Steam And Power: **10 Hours**

Steam generation in chemical plants. Types of boilers and waste heat boilers. Fuels-types, emissions and global warming, green fuels. Calorific value. Proximate and ultimate analysis. HHV, LHV and related calculations. Cogeneration power plants. CHPs and Boiler performance. Related Calculations. Economy of steam generation with different fuels, related calculation. Steam storage and handling-piping and accessories.

Refrigeration:

Different refrigeration systems and their characteristics. Air-conditioning systems. Coefficient of performance. Power requirements and refrigeration effect-related calculations for each type of refrigeration system. Refrigerant properties and selection. Some commonly used refrigerants and secondary refrigerants.

UNIT 3

Insulation: **10 Hours**

Insulation Materials & Selection-Economics of insulation. Insulating factors. Properties & Classification. Cold insulation and cryogenic insulation.

Introduction To Process Safety: Intrinsic & Extrinsic Safety. The Hazards-Toxicity, Flammability, Fire , Explosions. Sources of ignition, Pressure. Hazard and risk assessment methods. MSDS.

UNIT 4

Safety Devices: **10 Hours**

Pressure relief valves. Ruptures discs. Blow down systems. Flare systems. Flame arrestors. Deflagration arrestors and explosion suppression. Personal safety devices.

Process Safety Analysis:

HAZAN and HAZOP comparison.. Risk analysis and estimation. Safety check list. Computer based quantitative risk analysis.

Total: 40 hours

REFERENCE BOOKS:

1 Thermal Engineering, B.K. Sarkar, Tata Mc Graw Hill, 8th Reprint, 1998.
2 Heat Engines, K.P. Roy, Media Promoters and Publishers, 1995.
3 Power Plant Engineering, P.K. Nag, 2nd Edition, Tata Mc Graw Hill, 1998.
4 Water and Waste water engineering-Vol 2, Gordon M Fair, John C. Geyer and Daniel A Okun, Jhon Hutey,1996.

5 Water and waste water Technology, Mark J. Hammer Jr., 4th Edition, Prentice Hall, 1997.
6 Chemical Engineers Handbook, Perry, 8th Edition, 2007.
7 Chemical Engineering-Vol 6, R.K. Sinnot, Coulson and Richardson's, 3rd Edition, BH, Reprint, 2000.
8 Loss prevention in chemical process industries, Vol. 1,2,3, Frank P Lees, Butterworth-Heiremann,1980.

COURSE OUTCOMES:

1 Able to study Different utilities and Role of utilities in process plant operations.
2 Types of compressor and vacuum pumps.
3 Steam generation in chemical plants and Types of boilers.
4 Different refrigeration systems and their characteristics.
5 Process Safety analysis and Insulation Materials & Selection-Economics of insulation.

UBT824E: Metabolic Engineering
3 Credits (3-0-0)

UNIT 1

Introduction: **10 Hours**

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, AnapleroticPathways, 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 2

Metabolic flux: **10 Hours**

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 3

Regulation of Metabolic pathways: **10 Hours**

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 4

Metabolic Engineering in practice: **10 Hours**

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).

Total: 40 hours

REFERENCE BOOKS:

1 Metabolic Engineering – Principles and Methodologies by Gregory N. Stephanopoulos, Aristos
2 Aristidou, Jens Nielsen
3 P.F. Stanbury and A. Whitkar. Principle of Fermentation Technology pergaman press
4 Johnson and Thrins – Scaleup Methods in Chemical Engineering
5 M.L. Shuler and Kargi “Bioprocess Engineering basic concepts”
6 A.C. Bowden and M.L. Cardens “control of metabolic process” Plenum Publisher.
7 Wang D I C Cooney C I Demain, A L “Fermentation and enzyme Technology” John Willey

8 T. Roberts “Metabolism of Agrochemicals in Plants” Willey Int.
9 Zubey. G “Biochemistry” McMillon.
10 David L. Nelson and Michael Cox,“LehningerPrinciples of Biochemistry” –6thEdition,
11 LubertStryer, “Biochemistry” -Freeman & Co., Pub, 2010.

COURSE OUTCOMES:

1 Able to describe the Basic concept of metabolic engineering.
2 Explain Fundamentals of Metabolic flux analysis and its applications.
3 Discuss Regulation of metabolic pathways.

UBT825E: Industrial Waste Water Treatment
3 Credits (3-0-0)

UNIT 1

Water and wastewater engineering an overview **10 Hours**

Water quality, Physical chemical and biological parameters of water, water quality standards,water quality indices. Waste water: Terminology, impact of regulation on waste waterengineering, health and environmental concern in waste water management, waste water characteristics and treatment methods, current status and future trends, waste water reclamation and reuse, biosolids and residual management. Constituents of waste water, physical chemical and biological parameters of waste water, sampling methods, waste water effluent standards, sewage disposal methods.

UNIT 2

Primary and secondary treatment of wastewater **10 Hours**

Screens, oil traps, grit chambers, coagulation, clariflocculation, oxidation ponds and lagoons,Attached growth biological treatment : Activated sludge process and its modifications, trickling filter, biological nitrification and denitrification, anaerobic process, sludge disposal.

Advanced wastewater treatment

Removal of dissolved organic, inorganic constituents and biological constituents, Filtration: modeling and backwashing for slow sand and rapid sand filters, adsorption principle and isotherms, gas stripping, ion exchange, advanced oxidation process. Membrane filtration: RO, UF, MF, NF, electrodialysis. Disinfection: chlorine dioxide, chloramines, ozonation, UV radiation.

UNIT 3

Wastewater reclamation and reuse **10 Hours**

Waste water reuse application, need for water reuse, public health and environmental issues in water reuse, introduction to risk assessment for water reuse, different reuse options: Agriculture and landscape irrigation, industrial reuse, ground water recharge, non-potable uses with case studies.

UNIT 4

Issues related to treatment plant performance **10 Hours**

Need for upgrading treatment plant performance, treatment process reliability and selection of design values, odour management, introduction to automatic process control, energy efficiency, upgrading waste water treatment plant performance by process optimization, important design consideration for new waste water treatment plants: Liquid stream, solid processing, odour control .

Total: 40 hours

COURSE OUTCOMES:

1. Define water quality and explain methods to characterize water quality.
2. Describe water quality standards and their impact.
3. Explain primary and secondary treatment methods of waste water.
4. Apply membrane filtration techniques, and disinfection methods to purify waste water.
5. Analyze the importance of reclamation and reuse of waste water.
6. Describe methods of water reusage.
7. Identify various issues related to the performance of treatment plants and problems associated with them to combat them.

UBT827E: Pharmaceutical Biotechnology
3 Credits (3-0-0)

Prerequisites Biochemistry, Immunology, Microbiology.

UNIT 1

Introduction **10 Hours**

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 2

Toxicology **10 Hours**

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 3

Stem cells in health care **10 Hours**

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 4

Analysis of biologicals & pharmaceuticals **10 Hours**

Vitamins Cold remedies Laxatives Analgesics, Non-steroidal contraceptives, 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. Quality assurance and control.

Total: 40 Hours

Text books

1. Biopharmaceuticals Biochemistry and Biotechnology 2nd Edition by Gary Walsh, Wiley Pub(2013)
2. Basic & Clinical Pharmacology9th Edition by BartramG.Katzung,McGrawHill,2009

Reference Books

1. The Theory & Practice of Industrial Pharmacy 3rd Edition by Leon Lachman, Herbert A. Lieberman& Joseph &Kanig, Vergese Publishing House Bombay 1987
2. Pharmaceutical Biotechnology by K Sambamurthy & Ashutosh Kar, New Age, 2006.
3. Pharmaceutical Biotechnology by S P Vyas and V K Dixit, CBS Publishers, 2007
4. Developmental Biology, 6thEdition ScottF.Gilbert,2006
5. Molecular Biology of the Cell, 3rd Edition Bruce Alberts, Dennis Bray, Julian Lewis, Martin Raff, Keith Roberts, James D. Watson ,2006.
6. Stem Cell Biology by Marshak, Cold Spring Harbar Symposium Publication,2001

Course outcomes

1. Ability to classify various biological sources of pharmaceutical products to retrieve the basic concept of pharmacology, drug metabolism .and their importance in biotechnology
2. Ability to comprehend the toxicological studies of pharmaceutical products
3. Ability to interpret techniques used in the manufacture of pharmaceutical products
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. Ability to comprehend advanced techniques in drug delivery system.
6. Capable to discuss various other applications to protect the global community from various dreadful diseases.

UBT830E: Clinical Research
3 Credits (3-0-0)

UNIT 1

INTRODUCTION: **10 Hours**

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 2

THERAPEUTICS: **10 Hours**

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 3

HEALTHCARE MARKETPLACE: **10 Hours**

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 4

CLINICAL RESEARCH: **10 Hours**

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.

Total: 40 hours

Text Books

1 Biochemistry and Biotechnology by Gary Walsh. (2002): John Wiley & Sons Ltd.

Reference Books

1 Principles and Practice of Clinical Research by J. I. Gallin and F. P. Ognibene, 2nd Edition, Elsevier Publication,2007
2 Fundamentals of Clinical Trials by Lawrence M. Friedman 4th Edition, Kindle Edition, 2011

3 The Comprehensive Guide To Clinical Research: A Practical Handbook For Gaining Insight Into The Clinical Research Industry by Dan Sfera , Chris Sauber , Kindle Edition ,2019
4 Designing Clinical Research 4th Edition, by Stephen B. Hulley , Steven R. Cummings ,Warren S. Browner ,Deborah G. Grady , Kindle Edition,2013
5 *"Practical Guide to Clinical Data Management",* Third Edition, by Susanne Prokscha,2016

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
7 Ability to analyse the research principles from pharmaceutical industry perspective

UBT832E: Health Diagnostics
3 Credits: (3-0-0)

UNIT 1

INTRODUCTION: **10 Hours**

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 2

BIOCHEMICAL DIAGNOSTICS: **10 Hours**

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 3

IMMUNODIAGNOSTICS: **10 Hours**

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 4

IMAGING DIAGNOSTICS: **10 Hours**

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.

Total: 40 hours

Text Books

1 The Science of Laboratory Diagnosis, by John Crocker and David Burnett, 2007

Reference Books

1 Tietz Textbook of Clinical Chemistry, Carl A. Burtis, Edward R. Ashwood, Harcourt Brace & Company Asia Pvt. Ltd, 2013
2 Tietz Textbook of Clinical Chemistry, Carl A. Burtis, Edward R. Ashwood, Harcourt Brace & Company Asia Pvt. Ltd, 2013
3 Commercial Biosensors: Applications to Clinical, Bioprocess, and Environmental Samples Graham

Ramsay, John Wiley & Son, INC. (1998)
4 Essentials of Diagnostic Microbiology
5 Bailey & Scott's Diagnostic Microbiology

Course Outcomes:

1 Ability to studyBiochemical disorders, chromosomal disorders.
2 Able to study Dna based diagnostics.
3 Biochemical diagnostics and cell based diagnostics.
4 Immunodiagnostic and imaging diagnostics.

UBT833E: Validation & Quality Control
3Credits (3-0-0)

UNIT 1

Introduction: **10 Hours**

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 2

10 Hours

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 3

Implementation **10 Hours**

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 4

Quality **10 Hours**

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.

Total: 40 Hours

Text 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.
3. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed., 1998.

Reference Books

1. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance,2017
2. Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider, Saint Lucie,2017
3. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press, 1998.
4. 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

UBT834E: Product Development
3 Credits (3-0-0)

UNIT I

Essentials of product development **12 HOURS**

The product development process, privacy policies and Knowledge 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

Interpersonal Skills **10 HOURS**

Understand analyze and apply the techniques and essentials of product development and understand the various guidelines along with techniques in Pharma industries.

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

Reporting and formulations **10 HOURS**

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

Safety and Security at workplace **10 HOURS**

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.

Text Books

1. Endrenyi, L., Declerck, D. and Chow, S. (2017).
2. Biosimilar Drug Product Development. Boca Raton: CRC Press.
3. Biochemistry and Biotechnology by Gary Walsh. (2002): John Wiley & Sons Ltd.

References

1. 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.,
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 and understand the various guidelines along with techniques in pharma industry
2. Demonstrate the different inter personnel skills and project management skills
3. Ability to comprehend various techniques involved in reporting, decision making process and understand adverse effects of drugs.
4. Describe the formulation of various energy drinks and demonstrate the role of Upstream and Downstream marketing.
5. Analyze and list the various health hazards in industry.
6. Ability to understand importance of safety and implement in various industries.

QUESTION PAPER PATTERN OF CIE (Continuous Internal Evaluation):

1. CIE comprises of 3 tests, each of 30 marks and I hr duration, totaling to 90 marks and later is scaled down to 45 mark
2. Each CIE will be covering one and half unit
3. Any two full questions to be answered out of three questions and each question carries fifteen marks
4. Assignment: quiz/ objective tests etc carries five mark

QUESTION PAPER PATTERN of SEE:

1. Total of Eight Questions with Two from each unit to be set uniformly covering the entire syllabus.
2. Each question should not have more than four sub questions.
3. Any Five Full questions are to answered choosing at least one from each unit.

Laboratory Assessment:

1) Each laboratory subject is evaluated for 100 marks (50 CIE and 50 SEE)

2) Allocation of 50 marks for CIE

- Performance and Journal write-up: marks for each experiment = 30 marks/No. of proposed experiments.
- One practical test, for 20 marks (5 write-up, 10 conduction, calculation, Result etc., 5 –viva-voce)

3) Allocation of 50 marks for SEE

Major and Minor	: 35 marks (Write-up 25%, conduction 50%, calculation and results 25%)
Spotting	: 08 marks
Viva-Voce	: 07 marks