BASAVESHWAR ENGINEERING COLLEGE (A), BAGALKOTE

DEPARTMENT OF BIOTECHNOLOGY

Scheme and Syllabus

B. E. IV SEMESTER 2022-23

Sl. No	Category	Subject Code	Subject Title	Credits	HOURS/ WEEK			EXAMINATION MARKS		
					L	T	P	CIE	SEE	TOTAL
1.	BSC	22UBT401C	Biostatistics & Biomodeling	03	2	2	0	50	50	100
2.	IPCC	22UBT402C	Immunotechnology	04	3	0	2	50	50	100
3.	IPCC	22UBT403C	Heat & Mass Transfer	04	3	0	2	50	50	100
4.	PCC	22UBT404C	Molecular Biology	03	3	0	0	50	50	100
5.	PCC	22UBT405C	Bioprocess Principles and Calculations	03	3	0	0	50	50	100
6.	PCC	22UBT406L	Molecular Biology Lab	01	0	0	2	50	50	100
7.	HSMC	22UHS424C	CIP	01	1	0	0	50	50	100
			Total	**19**	**15**	**2**	**6**	**350**	**350**	**700**

SUBJECT CODE: 22UBT401C	BIOSTATISTICS & BIO-MODELING	Credits: 03
L: T: P - 2: 2: 0		CIE Marks: 50
Total Hours/Week: 40		SEE Marks: 50

UNIT-I	10 Hrs.

Introduction and Descriptive Statistics:

Scope of biostatistics, presentation of data, Diagrammatic and graphical represent,(simple, multiple, component bar diagrams, pie chart, histogram, frequency polygon, frequency curve, ogive curve). Measure of central tendency (meaning of central tendency, arithmetic mean, median, Quartiles, mode, geometric mean, harmonic mean their merits and demerits). Measure of dispersion: meaning, range, quartile deviation, mean deviation and standard deviation, coefficient of variation, skewness and kurtosis. Correlation and linear regression analysis, curve fitting straight line).

UNIT–II	10Hrs.

Probability and Probability Distributions:

Definition of probability, Event, Mutual Exclusive, Independent, Complimentary Events Addition and Multiplication theorem of probability and examples. Discrete probability distributions: Bernoulli's , Binomial and Poisson distribution. Continuous probability distribution – normal, Standard normal variate, properties of normal curve, T, F and $\chi 2$ (Chi square -goodness of fit test) distributions and their applications in Biology.

UNIT–III	10 Hrs.

Statistical Inference , ANOVA and Design of Experiments:

Estimation theory and testing of hypothesis point estimation, interval estimation. Sample, population, sample size determination. Methods of Sampling techniques- random (simple, stratified and systematic) non random sampling -(Judgement and convenience). Definition of analysis of variance(one way and two way classifications), Basic principles of experimental design and limitations-randomization, replication, local control, Types of statistical designs of biological experiments and limitations-CRD, RCBD, LSD, Plackett-Burmann design, Response surface methodology(RSM).

UNIT–IV	10 Hrs.

Bio-modeling:

Microbial Growth in a Chemo-stat, Growth Equations of Microbial Populations, product formation models, Models of Commensalisms, Batch culture model, Mutualism, Predation and Mutation. Simple Prey predator model, Volterra's Model for n Interacting Species. Basic Models for Inheritance, Applications of probability in genetics, Hardy - Weinberg law. Selection and Mutation Models, Genetic Inbreeding Models. Dose response studies.

Reference Books *

1. Khan and Khanum, (2008),Fundamentals of Biostatistics(3rd edition), Ukaaz Publication
2. Kapur J.N.(2001),Mathematical Models in Biology and Medicine(1st edition), New age international Pvt. Ltd.

3. Agarwal B.L. (2009), Basic statistics(5th edition), New age international Publishers
4. Rastogi V. B.(2006), Fundamentals of Biostatistics, Ane Books

Course Outcomes**

After completion of the course student will be able to

1. Interpretation of the data using different statistical methods.
2. Investigate the probability distributions of the data.
3. Design and analyze the experimentation using statistical tools.
4. Apply the biomodelling concepts in various biological studies.

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	-	3	2	-	-	-	-	3	-	2	3	2	-
CO2	2	2	-	3	1	-	-	-	-	2	-	-	3	1	-
CO3	1	3	3		3	-	-	-	-	2	-	2	3	-	-
CO4	3	2	-	2	2	-	-	-	-	1	-	2	2	2	-

SUBJECT CODE:22UBT402C	IMMUNOTECHNOLOGY	04 - Credits (3 : 0 : 2)
Hours / Week : 03		CIE Marks : 50
Total Hours : 40		SEE Marks : 50

UNIT – 1	10 Hrs.

The immune system:

Introduction, Cells and Organs of the immune system: Lymphoid cells, phagocytes, mast cells and dendritic cells. Primary (thymus, bone marrow and lymphatic system) and secondary Lymphoid organs (lymph nodes, spleen, MALT, CALT). Innate and adaptive immunity. Antigens, Antibodies, Complement system-complement activation,(classical, alternative and lectin pathway) regulation and biological consequences of compliment activation. Cytokines and their role in immune response.Monoclonal antibodies and applications.

UNIT – 2	10 Hrs.

Humoral and cell mediated immunity:

Introduction to humoral and cell mediated immunity. B-lymphocytes and their activation; Basic structure of immuno globulins; immunoglobulin classes (IgG, IgA, IgE, IgD and IgM) and biological activity. Antigenic determinants on immunoglobulin's- Isotype, Allotype and Idiotype. Thymus derived lymphocytes (T cells) and types, T-cell maturation and activation, mechanisms of T cell activation. Cell death and T-cell populations.Major Histocompatibility Complex and antigen presentation.Antigen presenting cells, dendritic cells, macrophages, mechanism of phagocytosis.

UNIT – 3	10 Hrs.

Immunological disorders:

Hypersensitivity reactions and its types. Autoimmune disorders- Organ specific, Systemic Autoimmune diseases, Animal models for autoimmune diseases and treatment of autoimmune disease. Primary and secondary immunodeficiency disorders (AIDS). Transplantation Immunology: immunological basis of graft rejection, Types of transplantations.

Vaccines: Active and Passive immunization. Designing vaccines for active immunization: Live, attenuated vaccines.Inactive vaccines, subunit vaccines, recombinant vector vaccines and DNA vaccines.

UNIT – 4	10 Hrs.

Immuno diagnosis:

Antigen-antibody reactions- Precipitation reactions, agglutination reactions, Blood typing A, B, ABO & Rh. Principal and applications of ELISA, Radio immuno assay (RIA), western blot analysis, immuno-electrophoresis, Non-isotopic methods of detection of antigens - Enhanced chemiluminescence assay. Purification and synthesis of antigens.Immuno-informatics

REFERENCES

1. Roitts Essential Immunology by Wiley Blackwell 13th edition 2017
2. Kuby J Immunology by, W H Freeman publishers 8th edition, 2019
3. Tizard and Thomson- An Introduction to Immunology 2004.
4. Ashim K and Chakravarthy- Immunology & Immunotechnology , Oxford University Press, 2006
5. Rastogi S C Immunodiagnostics New Age International.2005
6. Peter Wood Understanding Immunology, Pearson Education, II edition, 2006.

LIST OF EXPERIMENTS

1. Agglutination Technique: Blood group identification and Rh factor
2. Laboratory diagnosis of diseases-Widal test (Tube agglutination) and VDRL
3. Ouchterlony Double Diffusion (ODD)
4. Radial Immunodiffusion (RID)
5. Countercurrent immunoelectrophoresis (CCIEP)
6. Rocket immunoelectrophoresis (RIEP)
7. Western blot (IGg Purification)
8. ELISA/DOT Blot.

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**	**2**					**2**				**3**	-	**1**	**3**
CO 2	**2**	**2**	**1**	**3**	**2**	**-**	**3**	**-**				**3**	3	1	3
CO 3	**3**	**2**	**2**	2	**2**	**2**	**3**	**1**				**3**	**1**	**2**	2
CO 4	**2**	**2**	**2**			**1**						**2**	**2**	**3**	**2**

22UBT403C	HEAT AND MASS TRANSFER	03 - Credits (3 : 0 : 2)
Hours / Week : 03		CIE Marks : 50
Total Hours : 40		SEE Marks : 50

UNIT-I	10 Hrs.

Heat Transfer- I:

Modes of heat transfer; Conduction – steady state heat conduction through uni-layer and multilayer plane wall, sphere and cylinder; Forced and Natural convection; Significance of Dimensionless numbers (Nu, Gr, Pr, Re, Pe numbers only); Heat transfer to fluids without phase change; heat transfer in laminar and turbulent flow inside closed conducts.

UNIT–II	10 Hrs.

Heat Transfer- II:

Heat transfer with phase change - Condensation – film wise and drop wise; Boiling – types of boiling; Flow arrangements in Heat transfer equipment's - co current and counter current flow; LMTD, Elementary design of double pipe heat exchanger and shell and tube heat exchanger; Concepts of Heat transfer coefficients- Individual and overall; Fouling factor and Resistance for heat transfer

UNIT–III	10 Hrs.

Mass transfer Operations- I

Diffusion - Fick's law of diffusion; Measurement of diffusivity, Theories of mass transfer, Mass transfer coefficients and their correlations. Liquid-Liquid, Solid-Liquid, Liquid-Gas, Solid-Liquid-Gas Mass transfer. Principles, mass transfer considerations, operations like leaching, extraction, absorption, adsorption, crystallization and evaporation

UNIT–IV	10 Hrs.

Mass transfer Operations- II

Methods of distillation –Simple, Flash distillation of binary mixtures – relative volatility, fractionation of binary mixtures -McCabe Thiele method, Extractive and Azeotropic distillation, numerical. Drying: Drying rate, drying curve and calculations

LIST OF EXPERIMENTS (ANY 10)

1. Thermal conductivity of material (solid or liquid)
2. Heat transfer in a composite wall by conduction
3. Heat transfer by Natural Convection
4. Heat transfer by Forced convection
5. LMTD and Effectiveness in Heat Exchanger

6. Drop wise condensation
7. Film wise condensation
8. Diffusion
9. Distillation
10. Liquid-Liquid Extraction
11. Tray Dryer
12. Leaching

Reference Books *

1. McCabe WL, Smith JC and Harriott (2005) Unit operations in Chemical Engineering, 7th Edn., McGraw-Hill Publications, USA
2. Treybal RE (2012) Mass Transfer Operations, 3rd Edition, McGraw-Hill Publications, USA.
3. R.P. Chhabra V. Shankar (2018) Coulson and Richardson's Chemical Engineering Volume
4. Heat and Mass Transfer: Fundamentals and Applications, 7th Edition, Butterworth-Heinemann
5. Pauline Doran (2012) Bioprocess Engineering Principles, 2nd Edition, Academic Press
6. Alan S Foust, Wenzel LA, Clump CW, Maus L and Anderson LB (2008). Principles of Unit Operations, 2nd Edn. John Wiley & Sons, USA.
7. Kern (2001). Process Heat Transfer, 2nd Edn. McGraw-Hill Publications, USA.
8. Perry RH and Green DW (2008). Perry's Chemical Engineering Hand Book, 8th Edn. McGraw- Hill Publications.

Course Outcomes**

After completion of the course student will be able to

1. Define the different modes of heat transfer and solve the problems
2. Estimate the heat transfer rate for different types of heat exchangers.
3. Predict mass transfer rates and mass transfer coefficients.
4. Determine various parameters of mass transfer operations.

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	2	1							1	2		
CO 2	3	2	3	3	2							2	2		
CO 3	2	3	2	2	1							1	2		
CO 4	3	2	1	1	1							1	2		

SUBJECT CODE:22UBT404C	MOLECULAR BIOLOGY	03 - Credits (3 : 0 : 0)
Hours / Week : 03		CIE Marks : 50
Total Hours : 40		SEE Marks : 50

UNIT – 1	12 Hrs.

Introduction

Genes and their location. Information flow in biological systems: central dogma, updated central dogma. Signalling (signal transduction)-molecular mechanism. Reverse genetics, Genetic code-its features, codon and anticodon.

Replication:

Replication-basic concepts, structure and function of DNA polymerases, ligases, helicase. mechanism of DNA replication in prokaryotes and eukaryotes, End replication problem in eukaryotes, telomerase and its role, DNA damage & Repair (Photo reactivation, excision repair, recombinational repair, SOS repair).

UNIT – 2	10 Hrs.

Transcription

Mechanism of transcription in prokaryotes and eukaryotes, Bacterial RNA polymerase, structure and function of RNA polymerases (prokaryotes & eukaryotes), general transcription factors, post transcriptional processing, Si RNA, Antisense RNA technology.

Translation:

Protein synthesis: Initiators, Elongation factors, termination codons, Mechanism of translation, Structure and function of prokaryotic and eukaryotic ribosomes, Post translational modification. Differences between prokaryotic and eukaryotic protein synthesis, inhibitors of translation.

UNIT – 3	10 Hrs.

Gene Expression in Prokaryotes

Regulation of gene expression in prokaryotes: Operon model-structure and function, galactose and lactose operon, tryptophan Operon-regulation by attenuation mechanism; positive versus negative regulation, cyclic AMP effect/catabolite repression.

Gene Expression in Eukaryotes:

Regulation of eukaryotic gene expression, hormonal regulation- peptide and steroid hormones, transcriptional control, super secondary structures-Helix turns Helix. Zinc fingers and Leucine Zippers. Gene silencing- methylation, chromatin modification.

UNIT – 4	10 Hrs.

Transposons and Oncogenes

Transposons-replicative and non-replicative mechanisms, Insertion sequences, AC/DS elements, transposition in maize (Mc Clintock's work), Cut and paste transposition, Oncogenes and Protooncogenes, Tumour suppressor genes, retroviruses and its life cycle.

Genetic Recombination and Molecular markers:

Genetic recombination in bacteria- transformation, transduction and recombination, Mechanism of recombination-homologous (Holliday model), site specific recombination.

REFERENCES

1. David L. Nelson and Michael Cox, "Lehninger Principles of Biochemistry" –7th Edition, 2017
2. James D Watson "Molecular Biology of the Gene", 5th Edition, Pearson Edu.Pub.2008
3. David Freifelder "Essentials of Molecular Biology" Narosa Pub.House 2nd Edition. 2008
4. Alberts *et al* "Molecular Biology of the Cell" CBS Pub, 4th Edition, 2002.
5. NPTEL Source material

COURSE OUTCOMES

1. Emphasize on the basic aspects of molecular biology and classify the mechanism of DNA repair processes along with replication.
2. Acquire working knowledge on the mechanism of transcription, translation and post translational processes along with their applications in research.
3. Identify the various mechanism of gene regulation in prokaryotes and eukaryotes.
4. Identify the steps of transposition, Proto-oncogenes conversion and describe the molecular mechanism of genetic recombination.

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

22UBT405C	BIOPROCESS PRINCIPLES AND CALCULATIONS	03 - Credits (3 : 0 : 0)
Hours / Week : 03		CIE Marks : 50
Total Hours : 40		SEE Marks : 50

UNIT – 1	10 Hrs.

Units and Dimensions

Fundamental and derived quantities. Inter-conversion of units from one system to another. (FPS, CGS, MKS, SI).

Basic Chemical Calculations:

Concept of mole and molecule. Compositions of mixtures of solids, liquids and gases. Composition of mixtures and solutions: Percentage by weight, mole and volume; Normality, Molarity, Molality, and ppm.

Introduction to Bioprocesses:

Role of a bioprocess engineer in the biotechnology industry, outline of an integrated bioprocess and the various (upstream and downstream) unit operations involved in bioprocesses; Generalized process flow sheet and unit operations in chemical and bioprocess industries; General material balance equation for steady and unsteady states.

UNIT – 2	10 Hrs.

Material Balance without Chemical Reactions

Generalized material balance equations for distillation, absorption, extraction, crystallization, mixing, drying and evaporation, Material balances calculation in Distillation, Absorption, Extraction, Crystallization, Drying, Mixing and Evaporation Operations.

UNIT – 3	10 Hrs.

Material Balance Involving Chemical Reactions

Generalized material balance equations, Principles of stoichiometry, Definitions of limiting and excess reactants, fractions and percentage conversion, yield and percentage yield, Selectivity, unit process – neutralization, oxidation, hydrogenation, nitration, hydrolysis, esterification, alkylation and amination, problems relating to these unit processes.

UNIT – 4	10 Hrs.

Energy Balance

General energy balance equation for steady state. Thermo-physics and thermo-chemistry; Heat capacity, Estimation of heat capacity for solids, liquids, gases and their mixtures, Enthalpy, Standard heat of formation, Standard heat of reaction, Standard heat of combustion and calorific value. Calculation of delta H_R at elevated temperature. .

Stoichiometry of Microbial growth and Product formation

Stoichiometry of cell Growth and Product Formation- elemental balances, degrees of reduction of substrate and biomass; available-electron balances; yield coefficients of biomass and product formation

References

1. ntroduction to process calculation by K A Gavane, Nirali Publications,2016
2. Stochiometry by B.I.Bhatt and S.M. Vora, Tata McGraw Hill Publishing, 4th Edition, 2004
3. Basic Principles and Calculations in Chemical Engineering by David Himmelblau, PHI, 2005
4. Biochemical Engineering Fundamentals: by J. E. Bailey & D. F. Ollis (McGraw Hill),2005
5. Bioprocess Engineering by Shule and Kargi (prentice Hall), 2010
6. Principles of Biochemistry by David L. Nelson (Editors), 4th edition, W. H. Freeman and company Newyork, 2005.

COURSE OUTCOMES

1. Define the process operations and terms of calculations
2. Prepare the process flow diagram and identify the input and output streams
3. Apply the general procedure for solving the material balance problems
4. Apply the common skills and logical skills for solving material and energy balance

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	

SUBJECT CODE:22UBT406L	MOLECULAR BIOLOGY LABORATORY	01 - Credits (0 : 0 : 2)
Hours / Week : 02		CIE Marks : 50
Total Hours : 30		SEE Marks : 50

LIST OF EXPERIMENTS **10 Hrs.**

1. Study of standard practices in Molecular Biology Lab
2. Standard Operating Procedure for Centrifuge
3. Standard Operating Procedure for Gel documentation unit
4. Study of absorption spectra (proteins./ any biomolecule)
5. Agarose gel electrophoresis
6. Isolation of genomic DNA (plant / animal / microbial sources)
7. Isolation of plasmid DNA from *E. coli.*
8. Estimation of DNA by diphenylamine method.
9. Estimation of RNA by orcinol method.
10. Purity analysis of nucleic acids by UV-Vis Spectrophotometer.
11. PAGE - demo expt.

REFERENCES

1. Sadashiva and Manickam, "Biochemical Methods", 2nd Edition, New age international Publishers, 2004.
2. David Freifelder "Essentials of Molecular Biology" Narosa Pub. House, 2nd Edition, 2003.
3. James D Watson *et al*, "Molecular Biology of the Gene", 5th Edition, Pearson, 2007.
4. Darnell J Lodish & H Baltimore, "Molecular Cell Biology" -5thEdn. Freeman Pub, 2004.
5. Sambrook & Russell, "Molecular Cloning", 3rd Edition, Cold Spring Harber Lab.

LEARNING OBJECTIVES

COURSE OUTCOMES

1. Able to perform absorption spectra and understand SOP for various lab equipments
2. Able to analyze the concentration and purity of DNA
3. Able to conduct and analyze Agarose gel electrophoresis
4. Able to conduct observations and experiments including Genomic DNA/plasmid DNA /RNA/protein and Gain knowledge in demonstration of PAGE

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

VI SEMESTER-2022-23

Sl. No	Subject Code	Subject Name	Credits	Hours			Examination Marks		
				L	T	P	CIE	SEE	Total
1	22UBT615C	Enzyme kinetics and Biotransformation	3	3	0	0	50	50	100
2	22UBT616C	Upstream Processing Technology	3	2	2	0	50	50	100
3	22UBT617C	Bioprocess Equipment Design	3	2	2	0	50	50	100
4	22UHS003N	Career Planning and Professional Skills	1	1	0	0	50	50	100
5	22UBT62XE	Elective -2	3	3	0	0	50	50	100
6	22UBT63XE	Elective -3	3	3	0	0	50	50	100
7	22UXX6XXN	Open Elective-2	3	3	0	0	50	50	100
8	22UBT614L	Upstream Processing Lab	1	0	0	2	50	50	100
9	22UBT615L	Bio-kinetics & Enzyme Technology Lab	1	0	0	2	50	50	100
10	22UBT609P	Mini Project	3	0	0	3	50	50	100
Total			**24**	**20**	**4**	**7**	**550**	**550**	**1100**

Elective- 2

UBT621E Microbial BT

UBT623E Plant BT

UBT625E Biofuels technology

UBT627E Tissue engineering

Elective- 3

UBT631E Genomics & Proteomics

UBT632E Animal BT

UBT633E Pearl programming

UBT634E Transport phenomena

Subject Code: 22UBT615C	ENZYME KINETICS AND BIOTRANSFORMATION	3 Credits: (3: 0: 0)
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week: 40		SEE Marks: 50

UNIT-I	10 Hrs.

Enzyme action

Mechanism of enzyme action. Derivations of Km value (Michaelis-Menton constant), Lineweaver-Burk plot., Enzyme inhibition and kinetics

Multi-Substrate Reactions:

Introduction to enzyme catalyzed reaction Ping-pong mechanism, Sequential mechanism (ordered and random), Enzyme models - Host guest complexation chemistry.

UNIT–II	12Hrs.

Enzymatic Techniques

Strategies of purification of enzymes: choice of source, methods of homogenization, Criteria of purity: tests for purity, tests for catalytic activity, active site titrations, Molecular weight determination and characterization of enzymes.

Immobilization of enzymes:

Techniques of enzyme immobilization; design and configuration of immobilized enzyme reactions,Kinetics of immobilized enzymes**,** immobilized enzymes in bioconversion processes(uses). The design and construction of novel enzymes.

UNIT–III	10 Hrs.

Enzymes of biological importance

Enzyme pattern in diseases like in Myocardial infarctions (SGOT, SGPT, & LDH) Acetylcholinesterase, angiotensin converting enzyme (ACE), 5'- nucleotidase (5NT), glucose-6-phosphate dehydrogenase (GPD). Use of isozymes as markers in cancer.

UNIT–IV	10 Hrs.

Industrial uses of enzymes

Enzymes used in detergents, use of proteases, leather and wool industries; methods involved in production of glucose syrup from starch (using starch hydrolyzing enzymes).Uses of lactase in dairy industry, glucose oxidase and catalase in food industry. Uses of proteases in food industries.

REFERENCE BOOKS

1. Enzymes: Biochemistry , Biotechnology, Clinical Chemistry by Trevor Palmer, Horwood Publishing Ltd, East-West Press, 2nd Edition, 2008
2. David L. Nelson and Michael Cox, "Lehninger Principles of Biochemistry" –7th Edition 2017
3. Nicholas C. Price and Lewis Stevens Fundamentals of Enzymology , Oxford university Press,3rd edition, 2009
4. U. Sathyanarayana, "Biochemistry" -Books and Allied Pub,5th Edition,2017.
5. James R Hanson "An Introduction to Biotransformation in Organic Chemistry" Oxford university Press,1997.
6. Daniel L. Purich, Melvin I. Simon, John N. Abelson" Contemporary Enzyme Kinetics and Mechanism" Academic press, 3rd edition, 2009.
7. K. Faber" Biotransformations in Organic: Springer- Verlag.1st Edition, 1999.

8. Bailey and Ollis, “Biochemical Engineering Fundamentals”, Mcgraw Hill (2nd Ed.), 2017.
9. Plowman, ‘Enzyme Kinetics’ McGraw Hill, 2010

LEARNING OBJECTIVES

COURSE OUTCOMES

1. Ability to understand mechanism of enzyme reactions.
2. Ability to understand how to characterize the enzymes.
3. Ability to apply the techniques of immobilization of enzymes and know its uses.
4. Ability to know the importance of enzymes in diagnostics.
5. Ability to know the application of enzymes in wool, leather and detergent industries.
6. Ability to apply knowledge of using enzymes in food 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	3	3	1		2	3	2				3	3	2	3
CO 2	3	3	3	2		3	2	1				3	3	3	1
CO 3	3	3	3	2		2	3	1				3	3	3	1
CO 4	3	3	2	1		2	4	2				3	3	3	3
CO 5	2	3	2	3		1	3	2				3	3	3	3
CO 6	3	3	3	2		3	2	3				3	3	3	3

Subject Code: 22UBT616C	UPSTREAM PROCESSING TECHNOLOGY	3 Credits: (2: 2: 0)
L: T: P – 2-2-0		CIE Marks: 50
Total Hours/Week: 40		SEE Marks: 50

UNIT-I	10 Hrs.

Fermentation process

Range of fermentation processes, chronological development of fermentation industry, component of the fermentation process. Basic functions of a fermenter for microbial, plant and animal cell culture. Body parts of fermentor, aseptic operation and containment. Sterilization of fermentors. Classification of Fermentation Systems: Batch, fed batch and continuous process and their applications, Types of Fermentors.

Scale Up: Process engineering concepts, engineering considerations, mechanical considerations, energy considerations. Process GMP considerations of scale up, operations and quality.

UNIT–II	10Hrs.

Raw materials and media

Media requirement for typical fermentation process, selection of typical raw materials, types of fermentation media. Preparation and handling of fermentation media, sterilization and its practical limits, Batch sterilization, Continuous sterilization and Filter sterilization. Different methods for optimization (Plackett-Burman Design, RSM) of industrial media

UNIT–III	10 Hrs.

Microbial system

Isolation of industrially important microorganisms, Strain development methods, Preservation of industrially important microorganisms. Development of inoculum from laboratory scale to pilot scale and large scale fermentation (for bacterial, yeast, mycelial processes). Criteria for the transfer of inoculum. Aseptic transfer of inoculum to the fermentor. Trouble shooting during fermentation process (microbial contamination).

Secondary metabolite production: secondary metabolite production in bacteria, yeast and fungi. Production of lactic acid, butanol, antibiotics and enzymes.

UNIT–IV	10 Hrs.

Plant Cell system

Isolation and culture of single cells, Bioprocess using plant cell cultures. Bioreactors for suspension cultures, immobilized cells and organized tissues. Secondary metabolite enhancement techniques (alkaloids, steroids, phenolics).

Animal Cell system :

Scale up in suspension (stirred and static), monolayer (roller bottles, nunc cell factory microcarriers culture) and Perfusion culture (fixed and fluidized bed reactors).

Factors affecting cell culture,

Growth monitoring.

Genetically engineered cells for bioprocessing; process, selection of host vectors, process constraints- genetic instability, mass transfer and others.

Large scale production of insulin by mammalian cell culture.

Cellbank preparation & cell reviving techniques

Monoclonal antibody production: SUDBRCS (Single use disposable bioreactor configuration, types

of production (perfusion culture, submerged culture, suspended adhered culture).

REFERENCE BOOKS

1. Principles of fermentation Technology by P.F. Stanbury and A. Whitaker, Aditya books (P) Ltd. New Delhi 1997.
2. Bioprocess Engineering by Michael L. Shuler, 2nd Edition Shuler & Kargi, Fikret Kargi, Academic Internet Publishers, 2006
3. Introduction to plant Biotechnology by H.S. Chawla, Second edition, Oxford & IBH Publisher
4. Plant tissue Culture : Theory and Practice by S.S. Bhojwani and M.K. Razdan (1996). Elsevier
5. Culture of animal cells by Ian Freshney IVth Edition. John Willey & Sons Publ.
6. Animal Biotechnology by Murray Moo-Young (1989), Pergamon Press, Oxford

LEARNING OBJECTIVES

COURSE OUTCOMES

1. Understand and identify the component parts of fermentor and fermentation system
2. Select the raw material , prepare and sterilize the media and also to optimize the industrial media using Design of experiments
3. Develop/design the industrially important microbes for industrial scale processes
4. Operate the reactors for Plant, Animal and GMOs

	Course Outcome	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO10	PO11	PO12	PSO 1	PSO 2	PSO 3
1	**Understand and identify the component parts of fermentor and fermentation system**	3	1											1	3	
2	**Select the raw material , prepare and sterilize the media and also to optimize the media using**	-	3												3	3

	Design of experiments															
3	**Develop/design the industrially important microbes for industrial scale processes**	2	2	3	1	1					2		1	3	3	
4	**Operate the reactors for plant, animal and GMOs**	2									3		1		3	

22UBT617C	BIOPROCESS EQUIPMENT DESIGN	3 Credits
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week: 40		SEE Marks: 50

UNIT-I	10 Hrs.
Process design of double pipe heat exchanger Introduction to heat exchanger, Functional design – Energy balance equation, log mean temperature difference (co-current, counter current), Heat transfer coefficients (inside, outside & overall), area, length, number of hair pins, diameter of tube. Pressure drop calculations. Detailed drawing of sectional front view of Heat exchanger.	
UNIT–II	**12Hrs.**
Process design of shell & tube heat exchanger Introduction to Heat Exchanger, Functional design – Energy balance equation, log mean temperature difference (co-current, counter current), Heat transfer coefficients (inside, outside and overall), area, length, number of tubes, tube sheet diameter, pitch type, diameter of tube sheet. Mechanical design – baffle, thickness of shell, thickness of tube sheet, thickness of head, pressure drop calculations – tube side and shell side. Detailed drawing of sectional front view of Heat exchanger (1-1, 1-2) with tube sheet layout.	
UNIT–III	**10 Hrs.**
Process design of fermenter Functional design- Based on the type of bioreactor (batch reactor& MFR) and cell growth kinetics and performance equation, determines the volume of the reactor, according to H/D ratio determine height and diameter. Mechanical design and different parts of fermenter; Detailed drawing of sectional front view of fermenter	
UNIT–IV	**10 Hrs.**
Process design of plate column distillation column Functional design- material balance, energy balance, height of the packed column using McCabe Thiele's method, Mass transfer coefficients, Diameter of columns (Top and bottom), top and bottom free space. Detailed drawing for the above design (showing clearly inlets, outlets liquid distributors, packing support)	
REFERENCE BOOKS	

1. Joshi, M.V., Process Equipment Design, Macmillan India, 1991.
2. Brownell, L.E. and Young, E.H., Process Equipment Design - Vessel Design, John Wiley and Sons, Inc.1959.
3. Ludwig, E.E., Applied Process Design for Chemical and Petrochemical Plants, Vol. 1 and 2, 3rd Ed., Gulf Publishing Co. 1997.
4. Indian Standards Institution, Code for Unfired Pressure Vessels, IS – 2825.
5. Bhattacharya, B.C, Introduction to Chemical Equipment Design, CBS Publications, 1985.
6. Perry's Chemical Engineers Handbook. 7th Edition Mc Graw Hill Publications

COURSE OUTCOMES

After completion of the course students are able

1. Apply the knowledge of design concepts of double pipe heat exchanger and their parts in Engineering applications
2. Apply the knowledge of design concepts of shell & tube heat exchanger and their parts in Engineering applications
3. Apply the knowledge of different types of bioreactors and their design concepts in Industrial applications
4. Apply the knowledge of design concepts of distillation column and their parts in Industrial applications

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	2	1							1	2		
CO 2	3	2	3	3	2							2	2		
CO 3	2	3	2	2	1							1	2		
CO 4	3	2	1	1	1							1	2		

Subject Code: 22 UBT625E	BIOFUELS TECHNOLOGY	3 Credits: (3: 0: 0)
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week: 40		SEE Marks: 50

UNIT-I	10 Hrs.

Biochemistry of biofuels and energy resources

Basic principle of light energy conversion to chemical energy &carbon fixation. Biochemistry involved in conversion of sugars to alcohols. Renewable and non-renewable resources.

Biofuels

Introduction to Biofuels - definition, advantages and disadvantages. Biofuel life cycle. Biomass as an energy core and its different mode of utilization. Conventional fuels and their environmental impacts. Modern fuels and their environmental impacts. Biofuel energy content. World scenario of biofuel production and use.

UNIT–II	12Hrs.

Biofuel feed stocks

Starch feed stocks-cereal grains, tubers & roots; Sugars feed stocks-sugarcane & sugarbeet; cellulosic feed stocks - forest residues, agricultural residues, Agricultural processing by-products, dedicated energy crops, municipal solid waste and paper waste. Lipid feed stocks :-Oilseed crops with examples, Algae, Waste oil, Animal fats. Next generation feed stocks. Environmental impacts of feed stocks.

Types of biofuels

First generation biofuels-vegetable oil biodisel, bioalcohols, bioethers, biogas syngas, solid biofuels. Second generation biofuels and third generation biofuels.

UNIT–III	10 Hrs.

Technologies for biofuels

Historical background. Biochemical platform – bioethanol production, standardization, emissions and properties of bioethanol. Thermochemical platforms - biodiesel production, standardization, properties and emissions of biodiesel. BtL fuels -production, properties and emissions. Biohydrogen processing and uses. Converting solid wastes to pipeline gas. Biomethanation, Microbial fuel cells. Blending of biofuels

UNIT–IV	10 Hrs.

Biofuels in perspective

Integrated refining concepts with reference to ethanol production. Economic feasibility of producing biodisel, Issues with biofuel production & use. Impact of biofuel in global climate change & food production. 1st versus 2nd generation biofuels.. Strategies for new vehicle technologies. Current research on biofuel production. Market barriers of biofuels.

REFERENCE BOOKS

1. Foster C. F., John ware D.A.Environmental Biotechnology by, Ellis Horwood Limited,

1987.
2. Larry Anderson and David A Fuels from Waste by Tillman. Academic Press, 1977.
3. Biotechnology, Economic & Social Aspects: E.J. Dasilva, C Ratledge & A Sasson, Cambridge Univ. Press, Cambridge, 2000
4. Environmental Biotechnology by Pradipta Kumar Mahopatra, 2007.

COURSE OUTCOMES

1. Ability to understand the basic principle involved in bioconversion process in energy
2. Able to define and differentiate the conventional fuels with biofuels
3. Able to diagnose the types of feed stocks used for biofuels.
4. Able to decide the feed stocks for different generation biofuels
5. Able to produce the biodiesel, bioalcohol and biogas using current technologies
6. Able to understand the various process to convert the solid waste to bioenergy
7. Able to understand current issues related with production and use of biofuels
8. Able to recall the Research opportunities and economic feasibility of the biofuels

SUBJECT CODE: UBT631E	GENOMICS AND PROTEOMICS	3 Credits
L:T:P – 3-0-0 N_L : N_T: N_P		CIE Marks: 50
Total Hours/Week: 4		SEE Marks: 50

UNIT-I	10 Hrs.

Introduction

Genes and Proteins, Polymorphisms – types of polymorphism, commercializing the Genome - Revenue opportunities: a) genome sequences and database subscriptions, b) prediction of new genes and their function by databases. c) prediction of new genes and their function by databases, d) potential revenue in the area diagnostic and biomedical applications, e) biosimilars market and implications.

Sequencing & genome projects: Early sequencing efforts. Methods of preparing genomic DNA for sequencing, DNA sequence analysis methods, Sanger Dideoxy method, Fluorescence method, shotgun approach. Next generation sequencing Genome projects on *E.coli*., Arabidopsis and rice; Human genome project.

UNIT–II	10 Hrs.

Functional Genomics

Gene variation and Single Nucleotide Polymorphisms (SNPs) genotyping tools -DNA Chips, comparative genomics. Functional genomic studies with model systems such as Drosophila, Yeast or C. elegans. Applications in Functional genomics, medicine and Gene Knockdown. Metagenomics-definition & concept. C-Value and paradox of genomes, Repetitive and coding sequences, Genetic and physical maps, chromosome walking Methods of molecular mapping, Marker assisted selection, map based cloning, Bioinformatics analysis- clustering methods. Approaches to physical mapping

UNIT 3	10 Hrs.

Structure of Proteins

Conformational analysis and forces that determine protein structures, geometries, phi, psi, omega angles, Ramachandran diagram, allowed chi angles of side chains in proteins, hydrogen bonding, disulphide bonds, Vanderwaal's force , salt bridges hydrophobic interactions, alpha helices, beta sheets, helix to coil transition, general features and thermodynamic aspects of protein folding, folding kinetics, protein-ligand interactions (Examples of bio-molecular interactions), fibrous proteins (structure of collagen, keratin) and Quaternary structures.

UNIT–IV	10 Hrs.

Proteomics

Introduction to proteomics, Sample preparation, protein extraction Denovo protein synthesis, LCMS/MS, M/Z ratio, sequencing and identification, Predictive Methods using Protein sequences: Protein Identity based on composition, Related web based software (JPRED, PROSEC, NNPREDICT and SOPMA) Proteome analysis "Protein Chip" - interactions and detection techniques, two dimensional PAGE for proteome analysis, Applications of proteome analysis to drug development and toxicology. Crisper-cas. Challenges in proteomics.

REFERENCE BOOKS *

1. Genetic Analysis – Principles, Scope and Objectives by JRS Finchman, Blackwell Science, 1st Edition,1994.
2. A M Campbell & L J Heyer Discovering Genomics, Proteomics & Bioinformatics –, Pearson Education, 2nd Edition, 2006.
3. Albala J S & I Humprey-Smith Protein Arrays, Biochips and Proteomics, CRC Press,1st Edition, 2003.
4. Sabesan, Genomics & Proteomics –Ane Books, 2007. 5. Pennington S. R. and M J Dunn Proteomics.

COURSE OUTCOMES**

After completion of the course student will be able to

1. To know about genes, brief history, polymorphism, prediction methods, Biosimilars, business opportunities in diagnostic and medicine
2. Understand about the Human genome project, tools in DNA sequencing methods and other advanced techniques, Comparative genomics using model organisms, functional genomics of different organisms and molecular markers, gene and physical mapping techniques
3. To know about Protein structure analysis and molecular interactions
4. Analysis of proteins, quantification, sequencing, identification, protein predictive methods and proteomics in medicine

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

SUBJECT CODE UBT632N	ENVIRONMENTAL TECHNOLOGY	Credits: 03
L:T:P – 3:0:0		CIE Marks: 50
Total Hours/Week: 40		SEE Marks: 50

UNIT-I	10 Hours

Introduction:

Current Environmental Issues and scope of Environmental science and technology biogeochemical role of soil microorganisms, Bioconcrete, Environment Impact Assessment

Bioaccumulation of toxicants

Characteristics of Xenobiotics, Relationship of Bioaccumulation with Chemical Structure, Ecophysiology of Bioaccumulation Process of toxicants uptake, Factors affecting bioaccumulation, measurement of bioaccumulation

Sustainable future: Green building concept, Carbon foot print, crediting, trading and its calculation, Water foot print Rain water harvesting .

UNIT–II	10 Hrs.

Waste water treatment:

Waste water characteristics BOD, COD, Primary & Secondary treatment, nanofiltration. ultrafiltration and microfiltration Microbial removal of phosphorous and Nitrogen Wastewater treatment of industries like sugar factories, food industries, beverages industries, and distilleries.

Solid waste management

Basic aspects, general composition of municipal solid wastes, aerobic treatment, anaerobic treatment biogas generation Solid waste management. Hazardous wastes, Biomedical Wastes E waste management, MoEF rules.

UNIT–III	10 Hrs.

Bioleaching & Biomining:

Microbes in Bioleaching- types, methods of bioleaching, Microbial recovery of phosphate, petroleum.

Bioremediation:

Major contaminants of air, water and soil, Biomonitors of environment (Bioindicators), Bioremediation using microbes, Phytoremediation, Biofilms its applications Bio-stimulation of Naturally occurring microbial activities, Bio-augmentation

UNIT–IV	10Hrs.

Biofuels:

Definition, Renewable and nonrenewable resources Advantages and disadvantages of biofuels

Biofuel feed stocks-sugar starch, cellulose, lipid Types of biofuel- first, second and third generation

Technologies for bio-fuel production-transesterification, gasification 2G technology, Biomethanation, Issues of biofuel production and its use. Microbial fuel cells.

Biodiversity: Value of biodiversity, threats to biodiversity approaches of biodiversity conservation.

Reference Books *

1. Pradipta Kum Mahopatra, 2006, Text Book of Environmental Biotechnology, I K Publishers.
2. R C Dubey and D K Maheshwari,2013 Text book of Microbiology,
3. M Y Young ,2004 ,Comprehensive Biotechnology Vol 1-4 (Eds). Pergamon Press
4. EJ Dasilva, C Ratledge & A Sasson, 2003, Biotechnology, Economic & Social Aspects Cambridge Univ Press.
5. Indu Shekhar Thakur,2012,Environmental Biotechnology Basic concepts and applications, Second Edition, I K international Publishing House, Pvt, Ltd.

Course Outcomes**

1. Able to analyse the current environmental issues, scope of environmental Technology and understand the various sustainable future concepts.
2. Able to analyse the methods used in treatment of waste water and solid waste.
3. Able to understand the concept of bioleaching process and biomining activity
4. Able to analyse the types and methods used in cleaning of the environment by bioremediation.
5. Able to define the sources of biofuels and produce various biofuels
6. Able to analyse the need of conservation of biodiversity

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	1								1	1
CO2	2	3	1		1								2	2	2
CO3	3	2			1								2	3	2
CO4	2	2	1				1						2	3	1
CO5	2	1					3					2	2	2	2
CO6	2		1		2		1					2	2	3	2

Subject Code: 22UBT614L	UPSTREAM PROCESSING LABORATORY	1 Credits: (0: 0: 2)
L: T: P – 0-0-2		CIE Marks: 50
Total Hours/Week: 3		SEE Marks: 50

LIST OF EXPERIMENTS.

1. Callus Induction Technique- Stock preparation, Media preparation.
2. Explants preparation and inoculation technique.
3. Development of suspension culture from callus
4. Animal cell culture techniques
5. Artificial seed production (Auxiliary buds)
6. Production of secondary metabolite by shake flask studies; Comparison of yield in various media
7. Fed batch culture – Assessment of yield
8. Development of inocula; lag time effect
9. Study of operational functions of the fermentor
10. Production of Ethanol in fermentor – Study of Growth kinetics, product formation, substrate utilization

REFERENCE BOOKS

1. Plant Cell Culture: A Practical Approach by R.A. Dixon & Gonzales, IRL Press.2nd Edition,1995
2. Introduction to plant Biotechnology by H.S. Chawla, , Oxford & IBH Publishers, 3nd Edition,2018.
3. Culture of Animal cells-3rdEdition-R.IanFreshney.Wiley2010.
4. Principles of fermentation Technology by P.F. Stanbury and A. Whitaker, Butterworth-Heinemann; 3rdEdition,2016

LEARNING OBJECTIVES

COURSE OUTCOMES

1.Able to prepare/reproduce the protocols for the experiments
2.Able to produce callus using plant tissue culture techniques
3.Able to prepare the industrial media and inoculum for the fermentation process
4.Able to operate lab fermenter and prepare the fermentation process to study growth kinetics, substrate utilization and product formation
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

Subject Code: 22 UBT615L	BIOKINETICS & ENZYME TECHNOLOGY LABORATORY	1 Credits: (0: 0: 2)
L: T: P – 0-0-2		CIE Marks: 50
Total Hours/Week: 3		SEE Marks: 50

LIST OF EXPERIMENTS.

1. Isolation of alpha-amylase from sweet potato or saliva
2. Maltose calibration curve by DNS method
3. Determination of activity of Salivary alpha-amylase
4. Determination of Specific activity of an enzyme
5. Effect of pH and temperature on enzyme activity
6. Determination of Kinetics constants (Km & Vmax)
7. Urea calibration curve
8. Determine the activity of enzyme Urease
9. Effect of inhibitors on enzyme activity
10. Immobilization of enzyme and determination of immobilized enzyme activity
11. (Prediction of % error, standard deviation need to be calculated from expt. no 5 and 6)

REFERENCE BOOKS

1. Laboratory manual of Biochemistryby Pattabiraman, 4th Edition, International Book Publishers, India, 2017.
2. Sadasivam and Manickam, Biochemical methods, 2nd Edition, New age International Publishers, 2017.

LEARNING OBJECTIVES

COURSE OUTCOMES

1. Ability to aquire knowledge how to isolate enzymesand plot calibration curves.
2. Ability to estimate the enzyme activity and specific activity.
3. Ability to evaluate the optimum pH and temperature required for enzyme activity.
4. Ability to analyze the effect of inhibitors for enzyme activity.
5. Ability to apply knowledge of Km & Vmax for enzyme activity.
6. Ability to immobilize enzymes and fine the activity of enzymes

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

VIII-SEMESTER-2022-23

Sl. No	Subject Code	Subject Name	Credits	Hours			Examination Marks		
				L	T	P	CIE	SEE	Total
1	UBT82XE	Elective -6	3	3	0	0	50	50	100
2	UBT83XE	Elective -7	2	2	0	0	50	50	100
3	UBT805P	Project	15	0	0	30	50	50	100
		Total	**20**	**5**	**0**	**30**	**250**	**250**	**300**

Elective-6

UBT823E: Chemical plant utilities & safety
UBT824E: Metabolic engineering
UBT825E: Industrial waste water treatment
UBT827E: Pharmaceutical BT

Elective-7

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

Subject Code: 22 UBT827E	PHARMACEUTICAL BIOTECHNOLOGY	3 Credits: (3: 0: 0)
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week: 40		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	10Hrs.

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, 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.

REFERENCE BOOKS

1. Biopharmaceuticals Biochemistry and Biotechnology 2nd Edition by Gary Walsh, Wiley Pub(2013)
2. Basic & Clinical Pharmacology9th Edition by BartramG.Katzung,McGrawHill,2009
3. The Theory & Practice of Industrial Pharmacy 3rd Edition by Leon Lachman, HerbertA. Lieberman & Joseph & Kanig, Vergese Publishing House Bombay ,1987
4. Pharmaceutical Biotechnology by K Sambamurthy & Ashutosh Kar, New Age, 2006.
5. Pharmaceutical Biotechnology by S P Vyas and V K Dixit, CBS Publishers, 2007
6. Developmental Biology, 6thEdition ScottF.Gilbert,2006.
7. Molecular Biology of the Cell, 3rd EditionBruce Alberts, Dennis Bray, Julian Lewis,MartinRaff, Keith Roberts, James D. Watson ,2006.
8. Stem Cell Biology by Marshak, Cold Spring Harbar Symposium Publication, 2001.

LEARNING OBJECTIVES

COURSE OUTCOMES

1. Ability to classify various biological sources of pharmaceutical products and their importance in biotechnology
2. Ability to retrieve the basic concept of pharmacology, drug metabolism .
3. Ability to comprehend the toxicological studies of pharmaceutical products
4. Ability to interpret techniques used in the manufacture of pharmaceutical products
5. Ability to discuss the concepts used in production of stem cells and analyse the applications and ethical issues of stem cells in the society
6. Ability to comprehend advanced techniques in drug delivery system.
7. Ability to analyse the components of drugs, symptoms of the disease and its cure
8. Capable to discuss various other applications to protect the global community from various dreadful diseases

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			3	1	3					3	2	1
CO 2	3	3	2	3	3	2	3	2					2	2	1
CO 3	2	2	3									2	3	2	
CO 4	3	3	2									3	2	2	
CO 5	3	3	3									3	2	3	
CO 6	1	2	2	3	3	3	2	3				3	2	2	3
CO 7	2	2	3	2	1	2	1	2				2	2	3	1
CO8	2	2	3	1	2	1	1	2				2	2	3	2

Subject Code: 22 UBT833E	VALIDATION & QUALITY CONTROL	3 Credits: (3: 0: 0)
L: T: P – 2-2-0		CIE Marks: 50
Total Hours/Week: 40		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

Subject Code: 22 UBT834E	PRODUCT DEVELOPMENT	3 Credits: (3: 0: 0)
L: T: P – 3-0-0		CIE Marks: 50
Total Hours/Week: 40		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			

Subject Code: 22 UBT835E	VALIDATION & QUALITY ASSURANCE	3 Credits: (3: 0: 0)
L: T: P – 2-2-0		CIE Marks: 50
Total Hours/Week: 40		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.

LEARNING OBJECTIVES

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**