SHIVAJI UNIVERSITY, KOLHAPUR
BRANCH: BIOTECHNOLOGY ENGINEERING
CLASS: B.E. (Biotechnology Engineering)
Revised syllabus of B.E (Biotechnology Engineering)
(To be implemented from Academic Year 2016-17)
SEMESTER (VII)

Name of the Subject	Teaching Scheme (Hours/week)				Examination Scheme (Marks)				
	L	T	P	Total	Theory	TW	POE	OE	Total
1.Bioreaction Engineering	4	-	2	6	100	25	25	-	150
2. Process Engineering Costing and Plant Design	4	-	-	4	100	25	-	-	125
3. Pharmaceutical Biotechnology	4	-	-	4	100	25	-	-	125
4. Protein Engineering	4	-	-	4	100	25	-	-	125
5. Elective -1	4	-	-	4	100	25	-	-	125
6.Research Methodology	2	1*	-	3	-	25	-	-	25
7. Comprehensive Test~	-	-	1	1	-	50	-	-	50
8. Industrial Training #	-	-	-	-	-	25	-	-	25
9. Project Work Phase -1	-	-	4	4	-	50	-	-	50
Total	**22**	**1**	**7**	**30**	**500**	**275**	**25**	**-**	**800**

L: Lecture, T: Tutorial, P: Practical, TW: Term Work, POE: Practical Oral Exam, OE: Oral exam
*** Tutorials shall be conducted batch wise.**
~Objective tests based on the subjects from S.E. to B.E. level
 # Industrial training shall be completed at the end of 6th Semester and assessment work will be carried out in 7th Semester

Elective-1
1. Good Manufacturing Practices
2. Vaccine and BiosimilarTechnology
3. Genomic and Proteomics
4. Bioethics, Biosafety and IPR

SHIVAJI UNIVERSITY, KOLHAPUR
BRANCH: BIOTECHNOLOGY ENGINEERING
CLASS: B.E. (Biotechnology Engineering)
SEMESTER (VIII)

Name of the Subject	Teaching Scheme (Hours/week)				Examination Scheme (Marks)				
	L	T	P	Total	Theory	TW	POE	OE	Total
1.Bioprocess Modeling andSimulation	4	-	2	6	100	25	-	-	125
2. Bioprocesses	4	-	-	4	100	25	-	-	125
3.Industrial Organization, Managementand Entrepreneurship	4	-	-	4	100	25	-	-	125
4.Animal Biotechnology	4	-	-	4	100	25	-	-	125
5. Elective-2	4	-	-	4	100	25	-	-	125
6. Project Work Phase -2	-	-	4	4	-	100	-	75	175
Total	**20**	**-**	**6**	**26**	**500**	**225**	**-**	**75**	**800**

L: Lecture, T: Tutorial, P: Practical, TW: Term Work, POE: Practical Oral Exam,OE:Oral exam

Elective-2

1. Environmental Biotechnology
2. Food Technology
3. Metabolic Engineering
4. Medial Biotechnology

EQUIVALENCE OF OLD AND NEW SYLLABI (B.E.)

Old Examination	Sr. No.	Subject under old syllabus	New Examination	Equivalent subject under new syllabus
B.E. (Biotech. Engg)Sem-VII	1	Bioreaction Engineering	B.E. (Biotech. Engg) Sem- VII	Bioreaction Engineering
	2	Protein Engineering	B.E. (Biotech. Engg) Sem- VII	Protein Engineering
	3	Pharmaceutical Biotechnology	B.E. (Biotech. Engg) Sem- VII	Pharmaceutical Biotechnology
	4	Bioprocesses	B.E. (Biotech. Engg) Sem- VIII	Bioprocesses
	5	Elective- I	B.E. (Biotech. Engg) Sem- VII	Elective- I
	6	Comprehensive tests (On all subjects from S.E.to B.E.-I)	B.E. (Biotech. Engg) Sem- VII	Comprehensive tests (On all subjects from S.E.to B.E.-I)
	7	Industrial training	B.E. (Biotech. Engg) Sem- VII	Industrial training at end of 6th Semester (3Week)
	8	Project Work Phase – I	B.E. (Biotech. Engg.) Sem- VII	Project Work Phase - I

Old Examination	Sr. No.	Subject under old syllabus	New Examination	Equivalent subject under new syllabus
B.E. (Biotech. Engg)	1	Bio separation Processes	T.E.(Biotech.Engg) Sem- VI	Bioseparation Processes
	2	Bioprocess Modeling and Simulation	B.E.(Biotech.Engg) Sem- VIII	Bioprocess Modeling and Simulation
	3	Bioprocess Engineering& Economics	B.E.(Biotech.Engg) Sem- VII	Process Engineering costing and plant Design
	4	Animal Biotechnology	B.E.(Biotech.Engg) Sem- VIII	Animal Biotechnology
	6	Elective- II	B.E.(Biotech.Engg) Sem- VIII	Elective- II
	7	Project Work Phase – II	B.E.(Biotech.Engg) Sem- VIII	Project Work Phase - II

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VII
Paper No. 1- Bioreaction Engineering

Teaching Scheme:
Lectures: 4 Hours/Week
Practical: 2 Hours/Batch/Week

Examination Scheme:
Theory: 100 Marks
Term Work: 25 Marks
Practical Oral Exam: 25 Marks

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Course Objectives: This deal with the study of kinetics of chemical and bio chemical process and exposes the design of several types of reactions.

Course Outcomes:

1. Development of reaction rate expression by analysing given reaction rate data
2. Construction of mass balance and determine the size of the reactor for given conversion in biochemical reaction
3. Development of skills to choose the right reactor scheme to carry out single and multiple reaction
4. Understanding of Non ideal flow reactor modules

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Section I

Unit: 1

Reaction kinetics **(10 hrs)**

Reaction thermodynamics, order and molecularity of reaction, homogeneous and heterogeneous reactions,elementaryandnon-elementaryreactions,reactionyield,reaction rate, calculation of reaction rates from experimental data, general reaction kinetics for biological system, production kinetics in cell culture, kinetics of substrate up take in cell culture, growth kinetics with plasmid instability, kinetics of bi-substrate enzyme reactions, kinetics of enzyme deactivation.

Unit: 2

Single reactor system **(10hrs)**

Constant volume and variable reactors, batch operation of a well-mixed enzyme and cell culture reactor, fed batch operation of a well-mixed enzyme and cell culture reactor, continuous operation of well mixed enzyme and cell culture reactor, continuous operation of plug flow enzyme and cell culture reactor, autocatalytic reactions, recyclereactors-plug flow reactorandcontinuousstirredtankreactor,comparisonbetweenmajormodesofreactor operation, Transient Behaviour of Bioreactors- Stability analysis, Stability of the chemostat, Stability of chemostat with substrate inhibition, Operating diagram, Transient responses of the chemostat, control of the chemostat, Turbidostat operation, Nutristat operation.

Unit: 3

Multiple reactor system **(4 hrs)**

Continuous stirred tank reactors of equal size in series, continuous stirred tank reactors of unequal size in series, finding conversion in given system, determining the best system for a givenconversion.

Section-II

Unit: 4

Multiple reactions **(8 hrs)**

Simple reactions, step wise reactions, parallel reactions, series reactions, maximising in batch reactor, plug flow reactor and continuous stirred tank reactor, reactor choice for series reactions and series parallel reactions, reversible reactions.

Unit: 5

Design for multiple reactions **(8hrs)**

Reactions in parallel- qualitative and quantitative treatment of product distribution, selectivity. Reactions in series-quantitative discussion about product distribution in plug flow and batch reactor.

Unit: 6

Deviations from ideal reactors **(8 hrs)**

Conceptof non ideality, reasons of non ideality,RTDstudies, F curve, C curve, E curve, diagnosis of ills of flow reactors, micro& Macro fluid, conversion calculation for Macro fluid,modelling of non-ideal behaviour-dispersion model, tanks in series model.

Note- Discuss minimum 3 research papers based on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options.

List of Experiments: (Any 8)

Minimum eight experiments should be performed. Suggested list is as below

1. Study of first order reaction.
2. Inversion of sucrose.
3. Study of pseudo first order reaction- Acidcatalyzed hydrolysis of methyl acetate
4. Study of a second order reaction – Saponification of ethyl acetate.
5. Determination of Arrhenius parameters for amylase or invertase.
6. Study of homogeneous catalytic reaction, decomposition of hydrogen peroxide, acid catalyzed ester hydrolysis.
7. Batch fermentation of sucrose using invertase.
8. Study of PFR.
9. Study of CSTR.

10. Study of CSTR combination in first order reactions.
11. Study of F & C curves in CSTR.
12. Study of F & C curves in helical coil reactor.
13. Study of PFR & CSTR combination in second order reaction.
14. Study of rate of substrate uptake in cell culture.
15. Study of rate of product formation in cell culture.

Text and References Books:

1. Chemical Reaction Engineering- Levenspile, O. (Wiley)
2. Chemical Engineering Kinetics- Smith, J. ((McGraw Hill, New York)
3. Reaction Kinetics for Chemical Engineers- Walas, S.M. (McGraw Hill, New York)
4. Elements of Chemical Reaction Engineering- Scott. H. Fogler, (EES publication)
5. Biochemical Engineering Fundamentals- Bailey andOllis, (McGraw Hill, New York)
6. Bioreaction Engineering-Schergeri, K. (John Wiley)
7. Bioprocess Engineering: Basic Concepts – Shuler M.L., Kargi F. (Prentice Hall of India)
8. Process Biotechnology Fundamentals, Mukhopadhaya, S.N. (Viva Books Pvt. Ltd.)
9. Bioprocess Engineering Principles – Doran Pauline M. (Elsevier Pub.)
10. Biochemical Engineering- Blanch H.W. and Clark, D. S. (CRC Press)

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VII
Paper No. 2 -Process Engineering Costing and Plant Design

Teaching Scheme: **Examination Scheme:**
Lectures: 4 Hours/Week **Theory: 100 Marks**
Term Work: 25 Marks

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CourseObjectives:

1. To introduce the concepts like process design development, general design considerations, flow sheet synthesis and development and economics involved in selection of materials
2. To introduce the basic concepts of accounting like depreciation, interest and investment costs, profitability analysis, costing

CourseOutcomes:

1. To be able to generate and choose between alternative process designs and generate the final process flow sheet with mass, energy balances
2. To be able to evaluate the process options based on costing and profitability making use of BEP analysis

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Section – I

Unit: 1 **(10 hrs)**

General Plant Design Considerations –Pre-project objectives, Project classification, Plant location, Plant Layout, Health and Safety , Loss Prevention, Environmental Protection, Plant operation and control, patent consideration

Unit: 2 **(6 hrs)**

Flow sheet synthesis and development – Process Information, Input/output structure, Functions diagrams, Operations diagram, process flow sheet, use of softwares in process design

Unit: 3 **(8 hrs)**

Design and costing strategy-Optimum design, material selection and costing, equipment design and costing and design reports.Comprehensive case studies.

Section – II

Unit: 4 **(10 hrs)**

Analysis of Cost Estimation – Industrial Cash flow, Factors affecting investment and production cost,Capital Investment, estimation of capital investment, cost indexes, cost components in capital investment, methods for estimating capital investment, estimation of total product cost, gross profit, net profit and cash flow

Unit: 5 **(6hrs)**

Interest, Time value of Money, Taxes and fixed charges– Interest, cost of capital, time value of money, cash flow patterns, Income taxes, fixed charges

Unit: 6 **(8 hrs)**

Profitability, Alternative investments and Replacements – Profitability standards, methods for calculating profitability, alternative investments, replacements, practical factors in alternative investment and replacements analysis.

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options

Textbooks and Reference Books:

1. Plant Design & Economics for Chemical Engineers-M. S. Peters , K. D. Timmerhaus, R.E. West (McGraw Hill) Fifth edition
2. Chemical Engineering Design, Coulson & Richardson's Volume 6 – R.K. Sinnott (Elsevier Pub.)
3. Contemporary Engineering Economics – Chan S. Park (Perason Pretice Hall)
4. Bioseparation Science and Engineering – Harrison R.G., Todd P., Rudge S.R., Petrides D.P.(Oxford University Press)
5. Principles of Fermentation Technology – Stanbury P.F., Whitaker A, Hall S. J. (Aditya Books)
6. Biochemical Engineering Fundamentals, Bailey&Ollis. (McGraw Hill Book Co.)
7. Conceptual Design of Chemical Processes, Douglas, James M., (McGraw-Hill,International Editions)
8. A Guide to chemical Engg. Process Design & Economics" Gael D .Ulrich, (John Wiley & Sons)
9. Chemical Project Economics, Mahajani, V.V., (Macmillan Indian Ltd.)
10. Systematic Methods of Chemical Process Design, Biegler, L.T., I.E. Grossmann and A.W. Westerberg, (Prentice Hall ,Pearson Education)
11. Chemical Process: Design and Integration, Smith, R., (John Wiley and Sons, West Sussex, UK)
12. Chemical Engineers Handbook 5th ed R.H. Perry& C.H. Chilton, (McGraw-Hill Book Company).

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VII
Paper No. 3-Pharmaceutical Biotechnology

Teaching Scheme:
Lectures: 4 Hours/Week

Examination Scheme:
Theory: 100 Marks
Term Work: 25 Marks

CourseObjective: The major objective of this course is to acquaint students with fundamentals of biopharmaceuticals.

CourseOutcome: At the end of the course students will gain knowledge of nucleic acid technology, production and mechanisms of action of antibiotics, anticancer drugs and biopharmaceuticals.

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Section I

Unit: 1

Pharmaceutical products: (10 hrs)

Introduction, classification, biosynthesis, production and mechanism of action ofβ-lactams, cephamycin, lincomycin,peptide antibiotics, tetracycline, hybrid antibiotics, anticancer agents.

Unit: 2

Biopharmaceuticals: **(8 hrs)**

Introduction, the status of the industry, the problems ofbiopharmaceuticals: differences from new chemical entities (NCE), biopharmaceuticals willbe expensive to manufacture, biopharmaceuticals cannot be given orally and will have wrong pharmacokinetics, biopharmaceuticals cannot be subject to normal preclinical and clinical testing, the regulatory authorities will not know how to deal with biopharmaceuticals, biopharmaceuticals will not be accepted by physicians and their patients.

Unit: 3

Biopharmaceutical Product Development: Case Study: D2E7: **(8 hrs)**

Development of a humanantibody to tumour necrosis factor(TNF), expression system, bioreactor, clarification, capture, and fine purification, product characterization, drug product formulation, progress toward acommercially viable process, cell line and bioreactor improvements, transgenic expression system, high –capacity purification technologies.

Section II

Unit: 4

Growth factors (9 hrs)

Chemical description of hematopoietic growth factors – Pharmacology, Cellular sources and stimuli for release, Physiologic role of G-CSF, GM-CSF, EPO, SCF,

Thrombopoietins,Pharmaceutical issues, Clinical and practices aspects, Toxicities, Other uses and new formulation , Growth hormone

Unit: 5

Insulin (6 hrs)

Chemical description of insulin, Production of insulin using r- DNA technology, Pharmacology and formulation of insulin, Pharmaceutical consideration of insulin, Clinical and practice aspects of insulin.

Unit: 6

Nucleic acid technology (6 hrs)

Oligonucleotides; biochemistry, physiochemical properties of oligonucleotides and their chemical modification, Antisense technology; rationale for antisense technology, therapeutic antisense molecules, triplex technology, Aptamer technology, Gene therapy in HIV infection, ribozymes

Note-Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal option.

Text and reference books:

1. Understanding Biopharmaceuticals: Manufacturing and Regulatory Grindley, Jill E. Ogden
2. Comprehensive Biotechnology Vol.3. Murray Moo-Young (Permagon Press)
3. Pharmaceutical Biotechnology, 2nd Ed. By Crommelin D.J.A. & Sindelar R. D (Wiley-Blackwell)
4. A multi volume comprehensive treatise, Biotechnology second, completely revised edition,edited by H. J. Rehm and G. Reed in cooperation with A. Puhler and P. Stadler Volume .(Wiley-VCH)
5. Drug Targeting Organ-Specific strategies. By Grietje Molema and Dirk K.F. Meijer.(Wiley-VCH).
6. Drug Delivery and Targeting by A. M. Hillery, A. W. Lloyd and J. Swarbrick, (Harwood Academic Publisher)
7. Pharmaceutical microbiology edited by W.B. Hugo and Russel, 6th edition, (Blackwell Scientific publication).
8. Handbook of Pharmaceutical Biotechnology, Jay P Rho, Stan G Louie, (HaworthPress.Inc.)

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VII
Paper No. 4-Protein Engineering

Teaching Scheme:
Lectures: 4 Hours/Week

Examination Scheme:
Theory: 100 Marks
Term Work: 25 Marks

Course Objectives:

a. To learn the theory and practice of a variety of protein engineering methods
b. Apply this knowledge to engineer protein.

Course Outcomes:

a. Understanding of variety of protein engineering methods
b. Design and engineering of proteins

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Section I

Unit: 1

Protein folding and assembly (6hrs)

Protein folding pathways in prokaryotes and eukaryotes; Protein folding of single domain and multi-domain proteins; Inclusion bodies and recovery of active proteins, Osmolyte assisted protein folding; Thermodynamics and kinetics of protein folding, chemical modifications of proteins

Unit: 2

Protein structure (8hrs)

Levels of protein structure, Bonds involved in maintaining protein structure, Ramachandran Plot, spectroscopic techniques for the analysis of protein secondary and tertiary structure, Analysis of conformational stability of protein by gel electrophoresis and immunochemical methods

Unit: 3

Methods of protein engineering (10 hrs)

Random and Site directed mutagenesis, Various PCR based strategies for protein engineering, Gene Shuffling, Directed evolution strategy- Phage Display Systems, Cell Surface display systems, Cell free display systems, RACHITT, ITCHY.

Section II

Unit: 4

Design of novel proteins (12hrs)

Strategies forthedesignofstructure- Self-AssemblyofModularUnitsofSecondaryStructure, Ligand-inducedAssembly, Assembly of Peptides via Covalent Cross-linking, Assembly of Peptides on a Synthetic Template, ProteinDesign by BinaryPatterningofPolar

andNonpolarAminoAcids. Strategiesforthedesignoffunction- NovelFunctions by Retrofitting Natural Proteins, IncorporationofBinding Sitesinto theNovoProteins, DesignofCatalyticallyActiveProteins.All topics will deal with case studies

Unit: 5

Engineering of Therapeutic Proteins (8hrs)

Engineering of Antibodies, Human growth hormone (rHGH), human insulin, Tissue plasminogen activator (TPA) Erythropoietin (EPO), Interferon (IF), HPV Vaccine proteins

Unit: 6

Enzyme Engineering (4hrs)

Protein engineering to improve enzyme catalytic efficiency, protein engineering to improve enzyme stability,protein engineering to improve enzyme enantioselectivity.

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options

Text and references Books:

1. Protein Engineering- Pravin Kaumaya,
2. Protein Engineering and Design- Paul R.Carey (Academic Press)
3. Novel Therapeutic Proteins- Klaus Demobowsky (Wiley Publications)
4. Microcharacterisation of Proteins-Ronald Kellner(Wiley Publications)
5. Directed Molecular Evolution of Proteins- SusaneBrakmann (Wiley Publications)
6. Protein Biotechnology and Biochemistry-Walsh. G. (Wiley Publications)
7. Proteomics in Practice- Westermeier (Wiley Publications)
8. Protein Engineering Practices and Principles-Jeffrey L. Cleland (Wiley Publications)
9. Protein Structure, a practical approach- T.E. Creighton(Oxforduniversity press)
10. Protein Function, a practical approach-T.E. Creighton (Oxford university press)

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester VII (Elective -I)
Paper No. 5-Good Manufacturing Practices

Teaching Scheme:	**Examination Scheme:**
Lectures: 4 Hours/Week	**Theory: 100 marks**
	Term Work: 25 Marks

Course Objectives:

a. To review Good Manufacturing Practices
b. To understand how GMPs are integrated into Formal Management Systems for Industry
c. To understand the fundamentals of how cGMP's apply to the validation of commercial products
d. To have a good understanding of the industry standard guidelines.

Course Outcomes:

a. Students will understand the basic concepts of GMPs.
b. Students will understand the importance and its implication in Industry.
c. Students will be able to understand the fundamentals of GMPs
d. Students will study the industry standard guidelines

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Section- I

Unit: 1

An Introduction to Pharmaceutical GMP (9hrs)

Good Manufacturing Practices- Introduction, WHO guidelines on GMP for Pharmaceutical Products, History of Good Laboratory Practices, Quality Assurance in Good Laboratory Practices.

Unit: 2

Quality Standards and Quality Assurance in Pharmaceutical Industries (8hrs)

Quality standards- Advantages and Disadvantages, Concept of Quality Control and Quality Assurance- there functions and advantages, Quality Assurance and Quality Management in Pharma Industry, Customer requirement of Quality.

Unit: 3

Pharmaceutical Validation (9hrs)

Types of Validation, Scope and Importance of Validation, Limitations of Validation, Organization of Validation, Elements of Validation (Q, OQ, PQ and DQ), Cleaning Validation, Validation of Analytical procedures as per ICH guidelines.

SECTION II

UNIT 4: Good Manufacturing Practice in Food industries (10hrs)

Implications of cGMP and food plant sanitation. The regulation for cGMPs. Planning of plant sanitation program and construction factors.Hygienic design of food plants and equipment's.Sanitation in warehousing, storage, shipping, receiving, containers and packaging materials.Control of rats, rodents, mice, birds, insects and microbes. Cleaning and Disinfection: Physical, chemical and microbiological approach.

Unit: 5

Quality control in Food industries (10hrs)

Introduction to Quality control and total Quality control in the food Industry. Various Quality attributes of food such as size, shape, texture, colour, viscosity and flavour. Instrumental, chemical and microbial Quality control.Sensory evaluation of food and statistical analysis. Food Quality and Quality control including the HACCP system

Unit: 6

Government and Trade Standards of Quality (6hrs)

Federal Food and Drug law, FDA action, BSTI laws, FDA Food Safety Modernization Act (FSMA), National, International, Social organizations, e.g., FAO, WHO, UNICEF.

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options

Text and Reference Books:

1. Quality Control of Herbal Drugs- Dr.Pulok A Mukherjee (Business HorizonsPharmaceutical Publishers)
2. cGMP for Pharmaceuticals – Manohar A Potdar (Pharma Med Press)
3. Validation of Active Pharmaceutical Ingredients-Ira R Berry (CRC Press)
4. Guidelines on c GMP and Quality of Pharmaceutical Products- S.Iyer (DK Publication)
5. Quality Assurance and Quality Management in Pharmaceutical Industry- Y. Anjaneyulu (Pharma Book Syndicate)
6. Quality assurance in Analytical Chemistry, B. W. Wenclawiak., M. Koch. E. Hadjicostas,(Springer).

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester VII (Elective -I)
Paper No. 5-Vaccine and BiosimilarTechnology

Teaching scheme: **Examination scheme:**
Lectures - 4 Hours/Week **Theory- 100 marks**
Term work- 25 marks

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Course Objective

To introduce the students to vaccines and Biosimilar and their characterization using analytical methods along with case studies.

Course Outcome

The subject will impart fundamental knowledge of Biosimilar and vaccines to students which will help them to make career in biopharmaceutical industries.

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Section I

Unit: 1

Conventional vaccines: (6hrs)

Classification, live attenuated vaccines, non- living vaccines; whole organism, subunit vaccines, diphtheria and tetanus toxoid, Acellularpertusis vaccine, polysaccharide vaccine.

Unit: 2

Modern vaccine technologies: (10hrs)

Genetically improved live vaccines; genetically attenuated microorganisms, live vectors, genetically improved subunit vaccines; genetically detoxified proteins, proteins expressed in host cells, recombinant peptide vaccines, Antiidiotype antibody vaccines, synthetic peptide based vaccines, nucleic acid vaccines.

Unit: 3

Pharmaceutical considerations: (6hrs)

Production, formulation; additives, adjuvant and delivery systems, combination vaccines, characterization, storage.

Section II

Unit: 4

Biosimilars and its scenario (9hrs)

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

Unit: 5

Characterization of Biosimilar (**9hrs)**

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

Unit: 6

Case studies of Biosimilars **(9hrs)**

Case studies: Erythropoietin, Somatotropin, Interleukin-2, Interferon Granulocyte macrophage-CSF, DNase, Factor VIIa, Factor IX, Factor VIII, Activated protein C, Tissue plasminogen activator.

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options

Text and Reference Books:

1. Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues"byNiazi, Sarfaraz K. (CRC Press)
2. Biotechnology & Biopharmaceuticals Transforming Proteins and Genes into Drugs by Ho, Reedney J. Y., MiloGibaldi. (Wiley Liss)
3. Pharmaceutical Biotechnology, 2nd Ed. By Crommelin D.J.A. & Sindelar R.D (Taylor & Francis)

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester VII (Elective -I)
Paper No. 5-Genomics and Proteomics

Teaching Scheme:
Lectures: 4 Hours/Week

Examination Scheme:
Theory: 100 Marks
Term work-25 Marks

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CourseObjectives:

1. To introduce the students with solid foundation in the thrust area of Genomics and Proteomics.
2. Human genome and human genomic products and application.
3. To teach students proteomics and its application.

Course Outcomes:

The subject will impart fundamental knowledge of genomics and proteomics which will help them to make career in these industries.

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Section I

Unit: 1

Organization of the Prokaryotic and Eukaryotic Genomes (8hrs)

Definition of Gene; Genome, and Genomic structure;Size of vertebrate genome; Introduction to genome databases; Genomemaps and types; current sequencing technologies; partial sequencing; approach to geneidentification; gene prediction methods and software; Annotation of genome. REBASE,Genome diversity; Taxonomy and significance of genomes-bacteria, Yeast, *Caenorhabditis*,*Arabidopsis sp.*, etc.

Unit: 2

Genome Sequencing and Genomic Project (10hrs)

Mapping of Human Genome; Molecular mapping of genome; construction Physical map and land marks used in physical maps, Basics ofradiation hybrid maps; strategies of sequencing of the entire genome, annotation and analysis of genomesequences; sequence repeats, transposable and retro transposable elements, pseudogenes; geneanalysis; gene order; chromosome rearrangement; compositional analysis; clustering ofgenes; composite genes; Genetic novelty; Implication of human genome project; Single NucleotidePolymorphism (SNPs), detection and its implications; identification of land marks in human genome: preparation of libraries; post genome sequence; DNA polymorphism. Plant breeding process and genomic; Genetic sequence and genetic diversity; variation in gene expression and epigenetic functional molecular phenotype and direct gene variation.

Unit: 3

DNA Microarray (8hrs)

Steps for gene expression, concept of microarrays, methods for gene expression;DNA array for global expression profile; types of DNA array, array databases; tools formicroarray analysis; soft-finder, xCluster, MADAM, SAGE, microarray design, microarrayexperimentation, fabrication computational analysis of microarray data, applications of DNAmicroarray.

Section II

Unit: 4

Protein and Proteome Analysis (7hrs)

Introduction and scope of proteomics; Protein separation techniques: ion-exchange, size-exclusion and affinity chromatography techniques, Polyacrylamide gel electrophoresis; *Isoelectric focusing (IEF)*; Two dimensional PAGE for proteome analysis; Image analysis of 2D gels

Unit: 5

Protein Microarray (7hrs)

Introduction, proteome, proteomics, protein separation techniques; 2D Gel electrophoresis, liquid chromatography, affinity chromatography (for cell map proteomics); proteomeanalysis; mass spectroscopy and its uses in protein identification; MALDI-TOF-TOF, electrospray ionization(ESI), tandem mass spectroscopy (MS/MS), analysis, tryptic digestion andfingerprinting (PMF), expression proteomics (express profile); profiling and diagnostics, drugtarget discoveries.

Unit: 6

Protein –Protein Interactions (8hrs)

Introduction, yeast two-hybrid, high throughput techniques for yeast two-hybrid proteininteractions, computationally directed two hybrid screen, Phage display, computationaldetection of functional linkages between proteins; phylogenetic profile, domain fusion, geneneighbourhood, gene cluster, analysis of genome wide protein-protein interactions in yeast,genome wide yeast two hybrid analysis of other organisms, protein fragmentcomplementationassay Recombinant DNA technology: DNA cloning basics, Polymerase chain reaction, DNA fingerprinting, Human genome project and the genetic map.

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options

Text and Reference Books:

1. Princ**i**ples of **G**enome Analysis and Genomics-3rd edition 2003, S. B. Primerose and R. M. Twyman, Blackwell publishing company Oxford, UK.

2. Bioinformatics; A Practical guide to the analysis of Genes and Proteins. Edited by Andreas D. Baxevanis and Francis Ouellette.
3. Bioinformatics sequence and genome analysis.2nd edition, 2004, David Mount, Cold Spring Harbor Laboratory Press New York.
4. Introduction to proteomics tools for New Biology, 1st edition, D.C. Leibler, Humana Press, Inc., New Jersey, USA.

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester VII (Elective -I)
Paper No. 5 -Bioethics, Biosafety and IPR

Teaching Scheme:
Lectures: 4 Hours/Week

Examination Scheme:
Theory: 100 Marks
Term work-25 Marks

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CourseObjective: To introduce students to safety and ethical issues, about genetic modifications, stem cell research, patents and copyright aspects of the biotechnological products and processes.

CourseOutcome: After the completion of course, students will gain knowledge of safety and ethical issues, about genetic modifications, patents and copyright aspects of the biotechnological products and processes.

Section I

Unit: 1

Biosafety **(8hrs)**

Introduction; Historical Background; Introduction to Biological Safety Cabinets; Primary Containment for Biohazards; Biosafety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals

Unit: 2

Biosafety guidelines: **(8hrs)**

Government of India; Definition of GMOs & LMOs; Roles of institutional Biosafety Committee, RCGM, GEAC etc. for GMO applications in food and agriculture; Environmental release of GMOs; Risk Analysis; Risk Assessment; Risk management and communication; Overview of National Regulations and relevant International Agreements including Cartagena Protocol.

Unit: 3

Biosafety management: **(6hrs)**

Key to the environmentally responsible use of biotechnology. Ethical implications of biotechnological products and techniques. Social and ethical implications of biological weapon

Section II

Unit: 4

Introduction to intellectual property: (10hrs)

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

Unit: 5

Basics of patents and concept of prior art: (8hrs)

Introduction to Patents; Types of patent applications: Ordinary, PCT, Conventional, Divisional and Patent of Addition; Specifications: Provisional and complete; Forms and fees Invention in context of "prior art"; Patent databases; Searching International Databases; Country-wise patent searches (USPTO, esp@cenet(EPO), PATENTScope (WIPO), IPO, etc.)

Unit: 6

Patenting procedures: (7hrs)

National & PCT filing procedure; Time frame and cost; Status of the patent applications filed; Precautions while patenting – disclosure/non-disclosure; Financial assistance for patenting -introduction to existing schemes Patent licensing and agreement Patent infringement meaning, scope, litigation, Licensing and cross licensing FlavrSavr^{Tm}-Tomato as model case and case studies.

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options

Text and reference books:

1. BAREACT, Indian Patent Act 1970 Acts & Rules, (Universal Law Publishing Co.)
2. Genetic Patent Law & Strategy, Kankanala C. Manupatra Information Solution Pvt. Ltd., 2007
3. Patents, Subbaram, N. R., (Syndicate)
4. Biotechnology Emerging Trends, Selvin, J., Ninawe, A.S., Sugunan, V.S. and Sukumaran, N., (A.P. Lipton Biotech Books)
5. Basic Biotechnology by Ignacimuthu, S. (Tata McGraw-Hill)
6. Genetically Yours by Lim, H. A., (World Scientific)
7. Biotechnologies and Development, (UNESCO Publications)
8. A Biotechnologies in developing countries present and future, (UNESCO Publishers)
9. Intellectual property rights on Biotechnology, Singh. K (BCIL), New Delhi

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester VII
6. Research Methodology

Teaching Scheme: **Examination Scheme:**
Lectures: 2 Hours/Week **Term Work: 25 Marks**
Tutorial: 1 Hours/Batch/Week

CourseObjective:
The course will impart knowledge of objectives to perform research andinterpretation of experimental data.

CourseOutcome:
After the completion of course, students will able to design, conduct experiments and interpret researchoutcomes for academic and industrial needs.

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Unit: 1

Research and its Methodologies (With Examples) (4hrs)

Objectives of research; research process – observation, analysis, inference, hypothesis, axiom, theory, experimentation; Types of research (basic, applied, qualitative, quantitative,analytical etc); Features of translational research, the concept of laboratory to market (bench to public) and Industrial R&D.

Unit: 2

Research in Biotechnology (6hrs)

Biological systems and their characteristics that influence the type and outcome of research; Exploratory and product-oriented research in various fields of biotechnology (health, agri,food, industrial etc.). Types of expertise and facilities required; Interdisciplinary nature ofbiotech research; Sources of literature for biotech research

Unit: 3

Experimental Research: Basic Concepts in Design and Methodology (6hrs)

Precision, accuracy, sensitivity and specificity; major experimental variables, biochemicalmeasurements, types of measurements, enzymes and enzymatic analysis, antibodies andimmunoassays, instrumental methods, experimentalplanning – general guidelines

Unit: 4

Results and Analysis (6hrs)

Importance and scientific methodology in recording results, importance of negative results,Different ways of recording, industrial requirement, artifacts versus true results, types ofanalysis (analytical, objective, subjective) and cross verification, correlation with published results, discussion, outcome as new idea, hypothesis, concept, theory, model etc.

Unit: 5

Scientific and Technical Publication (4hrs)

Different types of scientific and technical publications in the area of biotechnology, and theirSpecifications, Ways to protect intellectual property – Patents, technical writing skills

Unit: 6

Journals (4hrs)

Standard of research journals - impact factor - citation index. Information retrieval - access to archives and databases, search engines - google, pub med - national informatics centre network services. Online data base library. Definition and importance of impact factor and citation index; Assignment in technical writing

Text and reference Books:

1. Essentials of Research Design and Methodology Geoffrey R. Marczyk, David DeMatteo,DavidFestinger, (John Wiley & Sons Publishers, Inc.)
2. Biochemical Calculations: How to Solve Mathematical Problems in GeneralBiochemistry, 2nd Edition, Irwin H. Segel, (John Wiley & Sons Publishers, Inc)
3. Guide to Publishing a Scientific paper, Ann M. Korner, (Bioscript Press).
4. Research Methodology by C.R.Kothari (New Age International)
5. Writing the doctoral dissertation. Davis, G.B. and C.A. Parker, 2nd edition, pp 160. (Barron's Educational Series)

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester VII
7. Comprehensive Tests

Teaching Scheme: **Examination Scheme:**
TEST: 1 Hours/Week **Term Work: 50 Marks**

Syllabus ofS.E.-I to B.E.-I Biotechnology Engineering

1. Objective type question based tests are to be conducted.
2. Every week 1 hr. test for 50 marks is to be conducted.
3. Schedule of comprehensive test should be displayed at the start of the semester.
4. Subjects from SE (Sem III) to BE (Sem VII) should be considered for above tests.
5. Related subjects should be merged on the basis of principle fields i.e. Microbiology,Biotechnology, Biochemistry, Biochemical Engineering, Mathematics etc.
6. Minimum eight tests should be conducted in the Semester and average of eight tests shouldbe considered for final marks.

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester VII

8.Industrial Training

Examination Scheme:
Term Work: 25 Marks

The concern student should complete the 4 week training at the end of the 6thsemester. Inthese four weeks, they have to work in the industries as a trainee and submit brief report. Theinternal marks shall be given on

1. **Type of work carried in the industries**
2. **Reports**
3. **Orals**

Report should consist of:

1. History
2. Raw material
3. Process flow chart
4. Equipment details
5. Production process details
6. Pollution control aspects
7. Quality control aspects
8. Cost of Production and profits
9. Suggestions for improvement
10. Safety Aspects

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester VII
9. Project Work Phase-1

Teaching Scheme: **Examination Scheme:**
Practical:4 Hours/Week **Term Work: 50 Marks**

The following initial work regarding the project in the first semester to be carried out.

The students are required to carry out one of the following projects.
1. Processes based Project: Manufacture of product.
2. Equipment based Project: Detailed design and fabrication of the equipment fora given capacity.
3. Experimental based Project: Experimental investigation of basic or appliedresearch problem.
4. Industrial problems: Any problem or project directly related to existing plants formodification of process or equipment or regarding pollution control and energyconservation under the guidance of a staff member.

Department should monitor the assessment procedure should be the same for all thestudents of the class.

The Project Work consists of collection of literature, study of the various process selection of the process, computation of material and energy balances, process design of important please of equipment, detailed design of one of the mainequipment, plant location and layout cost estimation, economic analysis, details of experimental set up, analysis of data, pollution control, safety marketing conclusion andrecommendations, bibliography, etc., as applicable to the individual problem.

The object of the project is to make use of the knowledge gained by the student at various stages of the degree course. This helps to judge the level of proficiency, originality and capacity for application of theknowledge attained by the student at the end of the course.

Each project batch should consist of maximum 3 project groups having maximum 9 students. Each projectgroup should work for minimum four hours/week.

For term-work (Internal) 50 marks, the assessmentwill be done by conducting seminars and orals during the semester

Suggested fields for project work

1. Fermentation based: Microbial fermentation, Animal cell fermentation, Plant cell fermentationCombitorial chemistry: Enzymatic processes
2. Microbial/enzymatic treatment of domestic and industrial waste water treatment.

3. Modeling and Simulation: Microbial fermentation, Waste water treatment, modeling genetic regulation (genetic switches, signal transduction, mixed cascadic systems), Insilico microorganisms (metabolic flux analysis, elementary mode analysis of metabolic fluxes),Insilco mammalian/animal organs, Virtual patients (analysis by top to bottom and bottomtop analysis)
4. Bioinformatics: Sequence homology, clustering of genes, parametric analysis for homology and catalytic activity of enzyme, microarray data analysis.
5. Immunological studies: Modeling and experimental verification of antigenantibodyinteractions (steady state and dynamic modeling).
6. Metabolic Engineering and Genetic Engg. (modeling and experimental aspects of metabolic flux analysis for inhibitor development and planning for genetic mutation/deletion/strain improvement)
7. Toxicological studies: Effect of synthetic and plant extracted active compounds on eukaryotic organisms (Yeast and animal cells).
8. Extraction and purification techniques: Solvent/supercritical extraction of biologically active compounds from plants and herbs, Chromatographic purification.
9. Nutritional analysis of local food components and linear programming for balance diet design for Kolhapur region.
10. Techniques development for the preservation of farmer's products (fruits and vegetables)and scale-up of exiting techniques such as ozonation , γ-rays preservation; Optimization of long term preservation of milk by supercritical carbon dioxide.
11. Food industry: Optimization/Modification of microbial processes of food industry,nutritional enrichment of food products.
12. Production of Bioinsecticides and pesticides
13. Insect cell differentiation and development.
14. Tran differentiation of stem cells.
15. Reproductive biotechnology: Artificial reproductive technology.
16. Trace proteins studies.
17. Biotransformation.
18. Tracer techniques for establishment of metabolic pathways.
19. Microbial desalting of sea water.
20. Microbial leaching of metals from ores
21. Linear programming for dose design.
22. Environmental Biotechnology: Hospital waste treatment
23. Leather tanning by natural products

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VIII
Paper No. 1-Bioprocess Modeling and Simulation

Teaching Scheme:
Lectures: 4 Hours /Week
Practical: 2 Hours /Batch/Week

Examination Scheme:
Theory: 100 Marks
Term Work: 25 Marks

Course Objectives:

1. To learn the importance of modelling and simulation in bioprocesses.
2. To develop mathematical models for bioreactors and process equipment.

Course Outcomes:

1. To learn different types of models and fundamental laws to develop bioprocess model.
2. To be able to develop models for bioreactors and others process equipment.

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Section I

Unit: 1

BioprocessModeland model building (8hrs)

Introduction of bioprocess modeling and simulation, Application and scope of bioprocess modeling and simulation, Fundamental laws: Continuityequation,energyequation,equationof motion,transportequation,equationof state,Phaseandchemicalequilibrium,chemicalkinetics,Modelbuilding.

Unit: 2

Types of models (8hrs)

Unstructured and structured models, Deterministic and stochastic models, Segregated and unsegregated models, Compartmental models (two and three), genetically structured models

Unit: 3

Analytical and Numerical methods (8hrs)

Linear Equations: Direct Methods- Gaussian Elimination and LU Decomposition; Iterative solution techniques-Jacobi-Method, Gauss-Seidel Method, Relaxation Method, Convergence of the techniques; Direct Methods for Solving Sparse Linear Systems- Block Diagonal Matrices, Thomas Algorithm for Tri-diagonal and Block Tri-diagonal Matrices; Optimization Based Methods-Gradient based Methods (Steepest and conjugate), Newton's Method; ODE-IVP: Implicit and Explicit, Numerical Methods Based On Taylor Series Expansion, Univariat and Multivariate RK method, Numerical Methods Based on Polynomial Interpolation (Predictor corrector),ODE-BVP: Finite Element Method (Galerkin method), Finite Difference Method

Section II

Unit: 4

Modeling of heat and mass transfer equipment (6hrs)

a) Heat exchanger

b) Distillation-continuous binary distillation, multi component steam distillation

c) Liquid liquid extraction-single batch extraction, continuous equilibrium stage extraction, multistage counter current extraction cascade

Unit: 5

Modeling of Bioreactors (6hrs)

Batch reactor, Fed batch reactor, CSTR, PFR, packed bed reactor, fluidised bed reactor.

Unit: 6

Examples of Mathematical Models (12hrs)

a) Modeling of fermentations

b) Modeling for activated sludge process

c) Model for anaerobic digestion

d) Metabolic flux analysis

e) Elementary mode analysis

f) Modeling of gene regulation (Genetic switches)

List of experiments:

1. Representation of transfer function and input-output models using commands.
2. Intro to Simulink and building a dynamic model for fermentation process with Simulink.
3. Performance analysis of fed batch and chemostat reactor – solution to set of ODE
4. Performance analysis of bioreactor using MATLAB – use of phase plane analysis.
5. Design of packedbed bioreactor.
6. Design of chemostat using Graphical User Interface.
7. RungeKutta 4^{th} for set of ODEs.
8. Finite difference method for solving ODEs

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options

Text and References Books

1. Process Modelling Simulation and Control for Chemical Engineers-Luyben W.L. (McGraw-Hill)
2. Numerical Methods and modeling for Chemical Engineers-Davis M.E. (Wiley)
3. Process Modelling-Denn M.M. (Wiley).
4. Nonlinear analysis in Chemical Engineering-Finalyson B.A.(McGrawHill)
5. Numerical Methods for Engineers- Chapra S.C., Canale, R.P.(McGraw-Hill)

6. Modeling and Simulation in Chemical Engineering- Franks R.E.G.(Wiley).
7. Chemical Engineering Dynamic Modeling with PC simulation-John Ingam, Irving J. Dunn (VCH Publishers).
8. Chemical Process Design, Analysis and Simulation- Kayode Coker A. (Gulf Publishing Company).
9. Process Dynamic, Modelling, Analysis, Analysis and Simulation-Wayne Bequette (Prentice Hall).
10. Modeling and Control of fermentation Processes-J.R. Leigh(Peter Peregrinus).
11. Application of simple structured I Bioengineering, and P55inAdvances In Biochemical engineering-A. Haerder and J. A. Roels (Springer-Verlag).
12. Biochemical Engg Fundamentals- J.E. Bailey and D.F. Ollis (McGraw Hill).
13. Biological reaction engineering: Dynamic modeling fundamentals with simulation examples-JiriE, Prenosil, Elmar Heinzle, John Ingham, Irving J.Dunn(Science).
14. Advances in biochemical engineering- Fiechter A., Ghosh T. K.,N. Blakebrough,(Springier-Verlag).
15. Development of sustainable bioprocess: modelling and assessment-Elmar Heinzle, Arno P.Biwer, Charles L. Cooney (Wiley Publishers).

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VIII
Paper No. 2-Bioprocesses

Teaching Scheme:
Lectures: 4 Hours/Week

Examination Scheme:
Theory: 100 Marks
Term Work: 25 Marks

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Course Objectives –

1. To identify and select strategies for strain and process improvement for various industrially important fermentative products.
2. To study upstream and downstream processes for industrial fermentations.

Course Outcomes –

After completing the course students will be able to,

1. Contribute in research and development programs at industrial level
2. Get acquainted with the overall bioprocess for industrially important products
3. Identify problems related to industrial production and encourage finding out biotechnological solutions(Production of each bio-product to be discussed with respect to upstream process details, History, microorganisms, biosynthetic pathway, fermentation process details, recovery, and flow sheet.)

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Section I

Unit: 1

Production of Industrial Chemicals (10hrs)

Fermentative production of Organic acids: --Lactic acid, Citric acid, Acetic acid, Gallic acid Production of Organic solvents:-Ethanol, Acetone-Butanol, Glycerol

Unit: 2

Health Care Products (6hrs)

Fermentative production of antibiotics: Penicillin, Streptomycin Steroid fermentation: Biotransformation

Unit: 3

Production of industrial Biochemicals (8hrs)

Production of Enzymes:Lipases, α–Amylases, Glucose isomerases, Proteases Production of Biosurfactants: Xanthan

Section II

Unit:4

Production of fine chemicals (10hrs)

Fermentative production of Amino Acid:L-glutamic acid, L-Phenylalanine, L-lysine, L- tryptophanFermentative production of Vitamins: Vitamin B_{12}, Vitamin C, Riboflavin. Production of pigments: Anthocyanins

Unit:5

Production of Food and beverages (8hrs)

Production of Single Cell Protein (SCP), Production of baker's yeast
Alcoholic beverages: Beer, Wine, Whisky

Unit:6

Production of Agricultural products (5hrs)

Production of Bio fertilizers and Bio pesticides, Biogas production from municipal sewage

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options.

Text and Reference books:

1 Comprehensive Biotechnology: Vol 3- M. M. Young. (Pergamon Press, Oxford)
2. A textbook of Industrial Microbiology: second edition- Wulf Crueger & Anneliese Cruger (Panima Publishing Corporation)
3 Biotechnology- KeshavTrehan (New Age International Pvt. Ltd)
4. Process Biotechnology Fundamentals- S.N. Mukhopadhyay, I. Campbell, F.G. Priest (Viva Books Ltd)
5. Industrial microbiology – Prescott & Dunn (Agrobios)
6. Microbiology for Sanitary Engineers – McKinney, Ross. E. (McGraw-Hill)
7. Safety in Microbiology- D.A. Shapton and R.G Board (Academic Press, London)
8. Modern Concepts of Biotechnology- H.D. Kumar (Vikas Publishing house Pvt. Ltd)
9. Process Biotechnology fundamentals – Mokhopadhyay S. N. (Anshan Publishers)

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VIII

Paper No. 3 -Industrial Organization, Management and Entrepreneurship

Teaching scheme: **Examination Scheme**
Lectures - 4 Hours/Week **Theory- 100 marks**
Term Work- 25 marks

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Course Objectives:

1. Biotechnology Engineering graduates will show the understanding of impact of engineering solutions on the society and also will be aware of contemporary issues at global context.
2. Biotechnology Engineering graduates will develop confidence for entrepreneurship, self-education and ability for life-long learning in biotechnology field and management.

Course Outcomes:

1. The student will demonstrate a deeper understanding of different areas of Industrial management.
2. Student will understand importance of entrepreneurship and will get knowledge of different supports provided by the government to start small scale industries.
3. Students will able to implement the management concepts to perform day to day activity when they will actually get into industry.

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Unit: 1

Principles of Management and Business Environment: **(5hrs)**

Management- meaning and importance, levels of management.

Business Environment- Introduction, internal environment, external environment, Globalization,

Unit: 2

Functions of Management: **(14hrs)**

Planning- meaning and importance, process of planning,

Decision making-Meaning, Importance, Types, process

Organizing- definition and concept, need and significance, Formal and Informal organization

Communication – definition and concept, importance, steps in communication, types, barriers to communication, ways of overcoming the barriers in communication

Motivation – concept, importance, techniques, Theories of motivation.

Leadership styles: definition and concept, importance, styles, qualities of good leadership.

Controlling- definition and concept, importance, process, control techniques.

Unit: 3

Personnel Management-staffing: (6hrs)

Definition, Importance, sources of recruitment, recruitment procedure, Training and development.

Section -II

Unit: 4

Materials Management: (6 hrs)

Definition, objectives, duties of material manager, importance,

Purchasing- definition, objectives, purchasing methods, vendor selection and rating.

Inventory control- definition, importance, components, types of inventories

Unit: 5

Marketing Management: (8 hrs)

Definition, marketing concepts, selling concept, marketing research procedure, market research approaches,

Advertising - definition, objectives, benefits, Drawbacks of advertising, advertising media's.

Unit: 6

Entrepreneurship development and small scale Industries (SSI): (12 hrs)

Definition and concept, Modern concept of an entrepreneur, qualities required to become entrepreneur, types of entrepreneurs, factors conductive for promoting entrepreneurship, reasons of entrepreneurial failure,

Entrepreneurship Development: objectives, EDP training.

Small Scale Industry – definition, objectives, importance, procedure to start small scale industry, Institutions offering assistance to SSI, Incentives offered to SSI, Problems of SSI.

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options.

Text and Reference Books:

1. Industrial and business Management, M.T. Telsang, (S. Chand and Co. New Delhi)
2. Organizational Mgmt. and Behaviour- N. K. Hukeri, (Electrosted publication. Satara)
3. Management- James A. F. Stoner, R. Edward Freeman,(prentice hall of India, New Delhi)
4. Management Today- principles and practice- Burton and Thakur(TATA McGraw Hill Pub., New Delhi)
5. Econoics- Benham, F., (Sir Issocpitham and Sons LTd., London)
6. Principles of Economics- Seth M. L., (L. N. Agarwal Pub., Agra)
7. Essentials of Management,Harold Koontz, Heinz Weihrich.(McGraw-Hill

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VIII
Paper No. 4 - Animal Biotechnology

Teaching scheme: **Examination Scheme**
Lectures - 4 Hours/Week **Theory- 100 marks**
Term Work: 25 Marks

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CourseObjectives:

1. To study various applications of Animal Biotechnology for product development, social use, industry, environment and medical use.
2. To study cells structure and physiology generally used in cell culture.
3. To prepare laboratory for cell culture, organ culture and embryonic c cell culture
4. To study cell lines, collect the information of cell lines.
5. To study types of cell cultures and their application.
6. To study tissue engineering.

CourseOutcomes:

1. To study the Animal Biotechnology and its applications to Biotechnology for the benefit of human beings.
2. To study IVF and its applications to Test tube Baby
3. Study of Animal tissue culture and its applications to Biotechnology & industry and medicine.
4. The student can able to identify problems related to industrial production and encourage finding out biotechnological solutions.
5. The student will apply research skills to postgraduate research and industrial investigation.
6. To study the Animal bioreactor its design & use in industry (scale up).
7. Use of monoclonal antibodies for research, pharmaceutical vaccine, hormone, enzyme production & RDT in industrial application

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Section 1

Unit: 1

Introduction to animal cell: **(8 hrs)**

Structure and organization of animal cells of organ system, Structure and behaviour of cancer cells. Cell signalling and energy metabolism. Structure of clone cell involved in In-vitro fertilization and embryo transfer. Transgenic & Knockout animals.

Unit: 2

Equipment's and Material for animal Cell Culture (7 hrs)

Design of cell culture laboratory Equipments, their use in cell culture, Ultra-pure water, reagents, preparation of media (Protocol), glasswares, culture vessels their sterilization. Preparation, dialysis and sterilization of serum, Bio-safety and Ethics.

Unit: 3

Basic Techniques of animal cell culture: (7 hrs)

Isolation of tissues, enzymatic and non-enzymatic disaggregation, Primary culture-Lymphocytes, Liver, mesenchymal cells, Embryonic stem culture and its application.Need and advantages of cryopreservation. Organotypic Culture.

Section II

Unit: 4

Subculture and Propagation (4 hrs)

Separation of viable and nonviable cells , Terminology and commonly used cells lines, contaminated cells lines.Subculture of monolayer cells and maintenance (Protocol) Subculture of cells growing in suspension and maintenance of subculture.

Unit: 5

Characterization of cell culture: (8 hrs)

Microscopic study and photography,Preparation of chromosomes for analysis, Fluorescence insitu, hybridization in the analysis of Genes and chromosomes. Isoenzyme analysisG-6-P (Protocol), LDH (Protocol), Transformation andfibroblast immortalization.Cytotoxicity testing.

Unit: 6

Cell and Tissue Engineering: (6)

Review of Cell source, Cell and Media,Chondrocytes M5CS. Biomaterial scaffold and seeding.Bioreactorsfor animal cell culture andCultivation, Monoclonal antibodies. Cell and tissue engineering.

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options.

Textand Reference Books:

1. Animal Cell Culture by John R.W. (Masters Oxford University Press)
2. Introduction to Cell and Tissue Culture by Jennie P. Mather and Penelope E. Roberts (Plenum Press, New York and London)
3. Molecular Biotechnology: Primrose.
4. Animal Cell Biotechnology: R.E. Spier and J.B. Griffiths (1988),(Academic press EACC Handbook).
6. Culture of animal cells; a manual of basic techniques, Freshney R. I. (1995) (John Wiley And Sons, USA)

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VIII (Elective-II)
Paper No. 5 - Environmental Biotechnology

Teaching scheme: **Examination Scheme**
Lectures - 4 Hours/Week **Theory- 100 marks**
Term Work: 25

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CourseObjectives –This course is designed

1. To teach students the scientific and engineeringprinciples of microbiological treatment technologies to clean up contaminated environments
2. To generate valuable resources for the human society

CourseOutcomes –After completing the course students can,

1. Contribute to the global environmental problems by identifying the appropriate waste treatment to the relevant problems
2. Develop engineering solutions to the social, economic and environmental problems.

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Section I

Unit: 1

Microbial Biodiversity **(8 hrs)**

Microbial diversity on earth: extent and importance, level of bacterial diversity, isolation strategies, fungal biodiversity: isolation and identification, Environmental cycles, Biotechnology of nitrogen fixation, Environmental genomics: Degradative plasmids, release of genetically engineered microbes in the environment.

Unit: 2

Biological control of air pollution **(4 hrs)**

Treatment technologies, Bio-filters and Bio-scrubbers for decontamination of polluted air

Unit: 3

Soil and Waste management **(12 hrs)**

Treatment of solid wastes- landfills, leachate treatment, composting, Biogas production

Management of agricultural soils:

Biofertilizer: introduction history, production of nitrogen fixing organisms *Rhizobium, Azotobacter*, Growth hormones (Gibberlic acid, Indole acetic acid) Bioinsecticides: Introduction, production of *Bacillus thuringenesis*, *Trichoderma*

Treatment of liquid wastes: Waste water characteristics, Fixed and suspended sewage treatment processes, Disinfection, Water quality testing

Section-II

Unit: 4

Bioremediation **(15 hrs)**

Definition, Types of bioremediation, *In-situ* and *Ex-situ* bioremediation techniques, Factors affecting bioremediation.

Biodegradation of xenobiotic compounds

Organisms involved in degradation ofchlorinated hydrocarbons, substituted simple aromatic compounds, polyaromatic hydrocarbons, pesticides, surfactants and microbial treatment of oil pollution.Concept of Bioaccumulation and Biomagnifications, Phytoremediation Technology

Microbial leaching: Extraction of metals from ores; Recovery of metals from solutions; Microbes in petroleum extraction

Unit: 5

Biofuels **(6 hrs)**

Energy crops, Plant derived fuels (Biodiesel), Bioethanol, Microbial Fuel Cell

Unit: 6

Environmental laws and policies **(4 hrs)**

Note: - Discuss at least three research papers on above topics.

Nature of Question paper-

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options.

Text and References books:

1. Manual of Industrial Microbiology and Biotechnology-Arnold Demain and Julian Davies, II Ed. (ASM Press Washington)
2. Wastewater Engineering treatment and reuse- Metcalf Eddy (Wiley Publications)
3. Introductory Practical Microbiology- Jaya babu Mudili (Alpha Science International Limited)
4. Microbial Ecology: Fundamentals and applications- Atlas Bartha, 4th Ed.(Dorling Kinderley , India Pvt. Ltd)
5. General Microbiology, H.G. Schlegel, 7th Ed.(Cambridge University Press)
6. Manual on Solid Waste Management (CPHEEO, Govt. of India)

SHIVAJI UNIVERSITY KOLHAPUR
B.E. Biotechnology Engineering
Final Year Engineering: Semester-VIII
Paper No. 5 - Food Technology (Elective-II)

Teaching Scheme: **Examination Scheme:**
Lectures: 4Hours/Week **Theory: 100 Marks**
Term Work: 25 Marks

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CourseObjectives –
This course aims
1. To educate the students about chemical, biochemical and microbiological characteristics of foods.
2. To learn and apply engineering principles and concepts in handling, storing, processing, packaging and distributing food and related products.
3. To understand and apply the principles and techniques of biotechnology in the production, processing and marketing of high quality food and dairy products in a global context.

CourseOutcomes –After completing the course students can,
1. Contribute the research and development programs at industrial level
2. Gain knowledge in different food processing operations involved invarious food manufacturing process to produce quality food products
3. Identify engineering solutions to the industrial problems

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Section-I

Unit: 1

Introduction **(7 hrs)**

World food demand and Indian scenario, constituents of food (Water, Carbohydrates, Fats and oils, Proteins), quality and nutritive aspects. Food additives. Introduction to FSSAI standards. Deteriorative factors and their control, preliminary processing methods and preservation operation. Introduction to Food Safety Management System (FSMS) and HACCP

Unit: 2 **(7 hrs)**

Production and utilization of food products

Milk and Milk products: Fluid Milk and some of its derivatives, Ice cream and related frozen desserts, Cheese and their varieties, reduced fat dairy products, Essential micro-organisms and Fermented milk products.
Meat, Poultry and Eggs: Meat and meat products, Poultry, Eggs
Sea Foods: Fish procurement, Marine fish, Shellfish, Fish byproducts, Contaminants in Fish Spoilage micro-organisms, treatmentanddisposal of foodprocessing wastes

Unit: 3 **(7 hrs)**

Major food ingredients in India

Cereal, grains, Legumes and oilseeds

Fruits and vegetables: General composition and properties, Harvesting and processing of fruits and vegetables**.**

Section-II

Unit: 4 **(7 hrs)**

Energy engineering in food processing

Generation of steam, Fuel utilization, Electric power Utilization, Process controls in Food processing, Systems for heating and cooling food products, thermal properties of foods, modes of heat transfer- freezing systems, Frozen food properties, freezing time, refrigeration system for food products

Unit: 5 **(7 hrs)**

Microbial growth and Food preservation

Processing Systems, Microbial Survivor Curves, Influence of External Agents, Thermal Death Time, and Spoilage Probability.

Preservation by heat and cold dehydration, concentration, frying, irradiation, microwave heating, sterilization and pasteurization, fermentation and pickling, packing methods.

Unit:6 **(7 hrs)**

Downstream processing in food industries and packaging

Electro dialysis Systems, Reverse Osmosis System, Types of Reverse- Osmosis and Ultra filtration, Drying Processes & Dehydration Systems, Dehydration System Design, Sedimentation and Centrifugation

Packaging: Introduction, Food Protection, Product contaminants, Product communication and product convenience, Mass transfer in packaging material, packaging material and product shelf life, Food canning technology, Heat sterilization of canned food.

Text and References Books:

1) F Food Science: 5th Edition-Potter, Norman N. (CBS Publishers & Distributors)
2) Fennema's Food Chemistry, Fourth Edition Srinivasan Damodaran, Kirk L. Parkin, Owen R. Fennema
3) Food Processing Technology: Principles and Practice by P J Fellows, Wood Head Publishing Limited.
4) Processing Fruits: science and Technology by Diane M. Barrette, Laszlo Somogyi, Hosahalli Ramaswamy
5) Fundamental s of Food Engineering by Stanley Charm.
6) Introduction to Food Engineering - R. Paul Singh,Dennis
7) Heid, J. L.andJoslyn,M. A. ,Fundamental s ofFood
8) Processing Operation,TheAVIPublishingCo;Westport
9) Heldman,D. R. ,Food Process Engineering,TheAVI Publishing Co;Westport ,1975.
10) Hal l, C. W; Farall, A. W.&Rippen, A. L ;EncyclopediaofFoodEngineering,VanNostrand-Reinhold.
11) Food Process Engineering-Heldman D. R. (AVI Publishing Co)
12) Food Processing and preservation- B. Sivsankar PHI Learning Pvt. Ltd.

SHIVAJI UNIVERSITY KOLHAPUR
B.E. Biotechnology Engineering
Final Year Engineering: Semester-VIII (Elective-II)
Paper No. 5 - Metabolic Engineering

Teaching Scheme: **Examination Scheme:**
Lectures: 4Hours/Week **Theory: 100 Marks**
Term Work: 25 Marks

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Section –I

Unit: 1

Basic concepts of metabolic engineering (4 hrs)

Introduction to various pathways. Primary and secondary metabolites.Medical and agricultural importance of secondary metabolites.

Unit: 2

Metabolic regulation and Metabolomics (11 hrs)

Induction-jacobmonod model, catabolite regulation, glucose effect, cAMP regulation,feed back regulation, regulation in branched pathways, differential regulation by isoenzymes,concerted feedback regulation, cumulative feedback regulation, energy charge, permeability,control passive diffusion, active transport group transportation.Bioinformatics for reconstruction of metabolic networks -metabolic pathwaysynthesis algorithms, examples of metabolic pathway manipulations, analyzing databases formetabolic pathways-KEGG

Unit: 3

Material and energy balances (7 hrs)

Stoichiometric models and matrix representation; the chemical reaction vector and energetic; material and energy balances revisited; basis for simplification of reaction; elementalbalances;component balances and the link with macroscopic measurements; examples of constructionof elemental and component balances, thermodynamics of cellular processes – new conceptsfor quantitative bioprocess research and development**.**

Section –II

Unit: 4

Metabolic flux analysis (10 hrs)

The theory of flux balances; Derivation of the fundamental principle; Degree offreedom and solution methods; Moore-Penrose inverse and Tsai-lee matrix construction, Examples of applications of flux analysis introduction Metabolic Control Theory; Controlcoefficients; Elasticity coefficients; Summation and connectivity theorems, Methods forexperimental determination of metabolic fluxes by isotope labeling

Unit: 5

Genetic regulation of metabolic flux (4 hrs)

Gene expression in response to environmental stimulus, genetic tools for altering geneexpression

Unit: 6

Application of metabolic engineering (8 hrs)

Case study in pharmaceuticals, Fermentation, environmental bioremediation

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options.

Text and Referencebooks:-

1. Wang.D.I.C Cooney C.L., Demain A.L., Dunnil.P. Humphrey A.E. Lilly M.D.,
2. Fermentationand Enzyme Technology, (John Wiley and sons).
3. Stanbury P.F., and Whitaker A., Principles of Fermentation Technology, (Pergamon
4. Press).
5. COMPUTATIONAL Modeling of Genetic and Biochemical Network, by James M Bower
6. &Hamid Bolouri.
7. Metabolic Flux analysis, by Valino.
8. Comprehensive Biotechnology, Vol-3, By Moo & Young.
9. Fundamentals of Biochemical Engg. by Baily &Olis.
10. Principles of Biochemical Engg. byAiba&Humphery.
11. Biotechnology, by Black & Bra.
12. Zubay G., Biochemistry, Macmillan Publishers, 1989.

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VIII(Elective-II)
Paper No. 5 - Medical Biotechnology

Teaching Scheme: **ExaminationScheme:**
Lectures: 4Hours/Week **Theory: 100 Marks**
TermWork: 25Marks

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CourseObjectives:

1. To provide students with comprehensive theoretical knowledge of microbial diseases of human including the spread of micro-organisms, disease causation, diagnosis and treatment of diseases of major significance to public health.
2. To acquaint students with clinical tests used in diagnosis of human diseases.
3. To provide students with a knowledge of application of nanotechnology in the medical field for treatment of human diseases.

CourseOutcome:

After completion of course students will gain knowledge of applications of nanotechnology in medicine and microbial diseases of human being including their diagnosis and treatment.

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Section 1

Unit: 1 **(8 hrs)**

Classification of pathogenic microorganisms: Leptospira, Brucella, *Bacillus anthracis*.

Medical parasitology: Amebiasis, Cytosporidiosis, Giardiasis, Malaria, Toxoplasmosis, Trichomoniasis.

Medical Bacteriology: Staphylococcus, Streptococcus & Enterococcus, Pneumococcus, Mycobacterium, Bacillus, Salmonella, Shigella, Pseudomonas & non- fermenters, Vibrio

Unit: 2

Medical Virology: **(8 hrs)**

Adenovirus, pox virus, Hepadenvirus, Arbovirus, Retroviruses, Medical mycology: Fungi, mold, Yeast, pathogenic Fungi, Superficial mycosis, Cutaneous mycosis, Systemic mycosis.

Unit: 3

Anemia, Stem cell, Bone marrow transplant & Antibiotics. **(8 hrs)**

Blood loss anemia, megaloblastic anemia, leukemia, necrosis & apoptosis. Stem cells or bone marrow transplant, Antibiotics: Classification of antibiotics, Combinations of antibiotics, doses, side effects & general principles for use of antibiotics.

Section II

Unit: 4

Hybridoma Technology & Forensics: (8 hrs)

Production of monoclonal antibodies.Human gene therapy: pathology of tuberculosis, Japanese Encephalitis, Dengue, Acquired Immunodeficiency Syndrome (AIDS), Introduction to forensics & its applications. Preparation of DNA sample, Approaches for DNA analysis-VNTR, Dot Blot, Base Sequence, Data Collection & Processing, RAPD, RFLP, Microarray etc.

Unit: 5

Nanomedical Biotechnology (8 hrs)

Types of nanoparticles, nanodevices, nanorobotics, microrobotics, microbiovers, nanomedicine for cancer & neurological disorders

Unit: 6

Diagnosis and Kit Development (8 hrs)

Use of enzymes in clinical diagnosis
Use of biosensors for rapid clinical analysis
Diagnostic kit development for microanalysis

Note: Discuss at least three research papers on above topics

Nature of Question paper:

1. There will be two sections carrying 50 marks each.
2. Each section should have three questions having internal options.

Text and reference book:

1. Medical Biotechnology by JuditPongracz, Mary Keen Publisher: (ELSEVIER HEALTH SCIENCES)
2. Textbook of Medical Microbiology- Ananthnarayan et al.
3.Concepts in Biotechnology By Balasubramanian, Bryce, Dharmalingam, Green &Jayaraman (ed), (University press, 1996.)
4.Monoclonal antibodies: Applications in clinical oncology (Chapman & hall Medical, London)

SHIVAJI UNIVERSITY KOLHAPUR
B.E.Biotechnology Engineering
Final Year Engineering: Semester-VIII
6. Project Work Phase-2

Teaching Scheme:	**Examination Scheme:**
Practical: 4 Hours/Week	**Term Work:100Marks**
	POE: 75 Marks

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1. Project selected in first semester is to be continuing in second semester.
2. Minimum two progress reports to be submitted to guide throughout the semester.
3. Seminar on basis of project progress is to be given.
4. Evaluation on above basis marks is to be given.
5. For evaluation of external examination one external examiner is to be invited fromother university or Industry.