

**DR. A.P.J. ABDUL KALAM TECHNICAL UNIVERSITY
LUCKNOW**



**Evaluation Scheme & Syllabus
For**

**B.Tech. Fourth Year
(Biotechnology)**

On

Choice Based Credit System

(Effective from the Session: 2019-20)

DR. A.P.J. ABDUL KALAM TECHNICAL UNIVERSITY LUCKNOW

Study and Evaluation Scheme B.TECH. BIO-TECHNOLOGY (Effective from the session: 2019-20)

4th Year, 7th Semester

S. No.	Subject Code	Subject Name	Teaching Deptt.	L-T-P	Th/Lab Marks	Sessional		Total	Credit
					ESE	CT	TA		
1		Open Elective Course-I	Other Department	3-0-0	70	20	10	100	3
2	RBT-031-034	Departmental Elective-III	Core Department	3-0-0	70	20	10	100	3
3	RBT-041-044	Departmental Elective-IV	Core Department	3-1-0	70	20	10	100	4
4	RBT-701	Bioseperation & Down Stream Processing	Core Department	3-0-0	70	20	10	100	3
5	RBT-702	Environmental Biotechnology	Core Department	3-1-0	70	20	10	100	4
6	RBT-751	Bioseperation & Down Stream Processing Lab	Core Department	0-0-2	50		50	100	1
7	RBT-752	Environmental Biotechnology Lab	Core Department	0-0-2	50		50	100	1
8	RBT-753	Industrial Training	Core Department	0-0-3			100	100	2
9	RBT-754	Project-I	Core Department	0-0-6			200	200	3
	Total				450	100	450	1000	24

Departmental Elective-III

RBT-031: Genomics and Proteomics

RBT-032: Quality Control & Regulatory Affairs

RBT-033: Clinical Trials & Management

RBT-034: Bioprocess Economics & Project Management

Departmental Elective-IV

RBT-041: Chemical & Biological Thermodynamics (NPTEL)

RBT-042: Experimental Biotechnology (NPTEL)

RBT-043: Patent Laws for Engineers & Scientist (NPTEL)

RBT-044: Artificial Intelligence (NPTEL)

RBT-701: Bioseparation & Down Stream Processing

L	T	P
3	1	0

UNIT I - INTRODUCTION TO BIOSEPARATION PROCESS

(8)

Role and importance of bioseparation in biotechnological processes: RIPP scheme, Problems and requirements of bioproducts purification - Properties of Biomolecules - Characteristics of fermentation broth - Biological activity, Analysis of purity-Process economics: Capital and operating cost analysis.

UNIT II - REMOVAL OF INSOLUBLES

(8)

Cell disruption methods for intracellular products: Physical, chemical and mechanical - Removal of insolubles: Biomass and particulate debris separation techniques - flocculation - sedimentation - centrifugation and filtration methods.

UNIT III - ISOLATION OF PRODUCTS

(8)

Adsorption: Principles - Langumir - Freundlich isotherms - Extraction: Basics- Batch and continuous, aqueous two-phase extraction - supercritical extraction - *in situ* product removal - Precipitation: Methods of precipitation with salts - organic solvents and polymers - Membrane based separations: Micro and ultra filtration - theory - design and configuration of membrane separation equipments and its applications.

UNIT IV - PURIFICATION OF BIOPRODUCT

(8)

Basic principles of Chromatographic separations: GC-HPLC-gel permeation-ion-exchange-affinity- reverse phase and hydrophobic interaction chromatography-Electrophoretic separation techniques: capillary - isoelectric focusing-2D gel electrophoresis - Hybrid separation technologies: GC-MS and LC-MS.

UNIT V - PRODUCT POLISHING

(8)

Crystallization: Principles-Nucleation-Crystal growth-Kinetics-Batch crystallizers: Scale-up and design, Drying: Principles-Water in biological solids- Heat and mass transfer-Drying equipments: description and operation-Vacuum shelf - rotary dryer-Freeze dryer-Spray dryer. Biomolecules of Commercial importance Ethanol, citric acid, lysine, steroids, penicillin, dextran, trehalose, subtilisin, chymosin, vitamin B12, hepatitis B vaccine, insulin, erythropoietin, monoclonal antibodies.

TEXT BOOKS

1. Roger G. Harrison, Paul Todd, Scott R. Rudge, Demetri P. Petrides, "*Bio separation Science and Engineering*" Oxford University press, 2003.

2. Belter PA and Cussler E, "*Bioseparations*", Wiley, 1985.
3. Protein: Biochemistry and Biotechnology by Gary Walsh (2002 John Wiley & Sons Ltd.)
4. Process Biotechnology Fundamentals by S.N. Mukhopadhyay (2001). Viva Books Private Limited.
5. Schuler & Kargi, Bio-process Engg. PHI
6. Keith Wilson and John Walker, Practical Biochemistry—Principles and Techniques, Cambridge, 5th Ed.2000
7. Coulson & Richardson's Chemical Engineering – Volume 3 (Chemical and Biochemical Reactors and process controls) ed. Richardson, J.F., Peacock, D.G., First Indian ed. Asian Books Pvt. Ltd. 1998.
8. Bailey & oils, Biochemical Engg. Fundamentals, McGraw-Hill, 1990
9. Geankoplis, C.J. Transport Processes and Unit Operations Prentice Hall of (I) 3rd ed. 1997.
10. Mukhopadhyay, S.N. Process Biotechnology Fundamentals, Viva Books Pvt. Ltd. 2001.
11. Muni & Cheryan, Handbook of Ultrafiltration

REFERENCES

1. Raja Ghosh, "*Principles of Bioseparations Engineering*", World Scientific Publishing, 2006.
2. Ladisch.M.R, "*Bioseparation Engineering: Principles, Practice and Economics*", John Wiley & sons, New York, 2001.
3. Asenjo.J.M, "*Separation processes in Biotechnology*" Marcel Dekker Inc.1993.

RBT-702: Environmental Biotechnology

L	T	P
3	1	0

Unit I

8

Environmental pollution: An overview, Land, water , air , and noise, Marine (introduction , sources , effects and measurements). Thermal Pollution, Nuclear and Radiation Pollution, Type of Radiation, Radioactivity in nature, Decay chains, Toxic Hydrocarbon, Radioactive waste sunk, Genetic Consequences.

Unit II

8

Biological waste treatments and biofuel production. Microbiology of waste water treatments Methanogenesis: methanogenic, acetogenic, and fermentative bacteria – anaerobic and aerobic digestion processes and conditions. Minimal national standards for waste disposal. .

Unit III

8

Principles and design aspects of various waste treatments methods, with advanced bioreactor configuration : activated sludge process , trickling filter, fluidized expanded bed reactor , upflow anaerobic sludge blanket reactor , contact process , fixed / packed bed reactor , hybrid reactor , sequential batch reactor .

Unit IV

8

Kinetic models for biological waste treatment :bioconversion of agricultural and other highly organic waste materials into gainfully utilizable products – biogas, H₂, celluloses and food and feed stocks. Economical and social aspects of waste treatment.

Unit V

8

Bioremediation & Biomineralization: land , water ,Contaminated Soil, industries , organic contaminants , heavy metals. Bioconversion of cellulose, Hemicelluloses, Lignin (lignocelluloses), Bioleaching of ores, Recovery of metals.

Recommended Books:

1. Waste Water Engineering- Metcalf & Fuddy, 3rd ed.
2. Environmental Processes I-III, J. Winter, 2nd ed., Wiley Publications
3. Introduction to Waste Water Treatment- R. S. Ramalho, Academic Press.
4. Environmental Studies- Dwivedi & Mishra, Ed. 2007.
5. Environmental Biotechnology, B.C. Bhattacharya & Ritu Banerjee, Oxford Press, 2007.
6. Essentials of Ecology & Environmental Science, S.V.S. Rana, Prentic-Hall India, 2006.
7. Perspectives in Environmental Studies, Anubha Kaushik & C P Kaushik, New Age International Publishers, 2004.
8. Agarwal S.K. (1998), Environmental Biotechnology, APH Publishing Corporation, New Delhi.
9. Environmental Sciences – Purohit , Shammi & Agrawal, Student Edition 2004.

RBT-031: Genomics and Proteomics

L	T	P
3	0	0

Unit I

10

Introduction Structural organization of genome in Prokaryotes and Eukaryotes; Organelle DNA-mitochondrial, chloroplast; DNA sequencing-principles and translation to large scale projects; Recognition of coding and non-coding sequences and gene annotation; Tools for genome analysis-RFLP, DNA fingerprinting, RAPD, PCR, Linkage and Pedigree analysis-physical and genetic mapping.

Unit II

8

Genome sequencing projects Microbes, plants and animals; Accessing and retrieving genome project information from web; Comparative genomics, Identification and classification using molecular markers-16S rRNA typing/sequencing, EST's and SNP's.

Unit III

8

Proteomics Protein analysis (includes measurement of concentration, amino-acid composition, N-terminal sequencing); 2-D electrophoresis of proteins; Microscale solution isoelectric focusing; Peptide fingerprinting; LC/MS-MS for identification of proteins and modified proteins; MALDI-TOF; SAGE and Differential display proteomics, Protein-protein interactions, Yeast two hybrid system.

Unit IV **6**

Pharmacogenetics High throughput screening in genome for drug discovery-identification of gene targets, Pharmacogenetics and drug development

Unit V **8**

Functional genomics and proteomics Analysis of microarray data; Protein and peptide microarray-based technology; PCR-directed protein in situ arrays; Structural proteomics

Texts/References :

1. Voet D, Voet JG & Pratt CW, Fundamentals of Biochemistry, 2nd ed. Wiley 2006
2. Brown TA, Genomes, 3rd ed. Garland Science 2006
3. Campbell AM & Heyer LJ, Discovering Genomics, Proteomics and Bioinformatics, 2nd ed. Benjamin Cummings 2007
4. Primrose S & Twyman R, Principles of Gene Manipulation and Genomics, 7th ed, Blackwell [2006].
5. Glick BR & Pasternak JJ, Molecular Biotechnology, 3rd ed, ASM Press [1998]

RBT-032: Quality Control & Regulatory Affairs

L	T	P
3	0	0

Unit I **8**

Concept and evolution of quality control and quality assurance. Quality control laboratory responsibilities: GLP protocols on non-clinical testing control on animal house, data generation, integration and storage, standard test procedure, retention of sample records. CPCSEA guidelines.

Unit II **8**

Quality review and batch release document of finished products, annual product quality review and parametric release, Audits, quality audits of manufacturing processes and facilities, audits of quality control.

Unit III **8**

Good documentation practices, root cause analysis, corrective action preventive action (CAPA), out of specifications (OOS) and out of trend (OOT), Clinical studies- ICH GCP (E6) guidelines, post marketing surveillance, Pharmacovigilance

Unit IV **8**

BABE (bioavailability and bioequivalence) studies, Concepts and management of contract manufacturing guidelines, Statistical Tools for Quality Control and Precision, Tools of Problem Solving and Continuous Improvement

Unit V **8**

Introduction, scope and importance of IPR, Concept of trade mark, copyright and patents Product registration guidelines – CDSCO, USFDA, Concept of ISO 9001:2008, 14000, OSHAS guidelines, Quality Strategy for Indian Industry, Brief concept of IND, NDA, ANDA, SNDA and PAT.

References:

1. Sharp J. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance. CRC Press; 2005.
2. Chow SC. Encyclopedia of Biopharmaceutical Statistics. Marcel Dekker; 2003. Page 6 of 16
3. McCormick K. Quality (Pharmaceutical Engineering Series). Butterworth-Heinemann; 2002.
4. Gad SC. Pharmaceutical Manufacturing Handbook: Production and Processes. John Wiley & Sons; 2008.
5. Willig SH, Stoker JR. Good manufacturing practices for pharmaceuticals: a plan for total quality control. Marcel Dekker; 1997.
6. Signore AA, Jacobs T. Good Design Practices for GMP Pharmaceutical Facilities. Taylor & Francis Group; 2005.
7. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
8. Haider SI. Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance. St. Lucie Press; 2002.
9. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
10. Kolman J, Meng P, Scott G. Good Clinical Practice: Standard Operating Procedures for Clinical Researchers. Wiley; 1998.

RBT-033: Clinical Trials & Management

L	T	P
3	0	0

Unit-I **8**

General Introduction - Good Clinical Practices, Basics Of Drug Development - Basic Principles of Drug discovery & Development, Stages of Drug Discovery. Research for a new drug. Preclinical Research, Pharmacokinetics & Drug Disposition

Unit-II **8**

Ethics In Clinical Research - Ethical issues in the conduct of clinical trials in India, Readiness of ethics committees, Independence of ethics committees, Training for ethics committee members. Informed consent process.

Unit-III **8**

Regulatory Affairs In Clinical Research - Roles & Responsibilities, Pharmacovigilance researching, assessing and evaluating information from healthcare providers and patients. Pharmacovigilance is particularly concerned with adverse drug reactions. Adequacy of regulations to safeguard the clinical trial participants.

Unit-IV **8**

Essential Documents & Regulatory Submission, Compliance And Audits - preparation, production and quality control of regulatory documents, creating editorial timelines and work flow specifications, scheduling and tracking documents, writing and proofreading. Development and updates on specifications for the design, tracking of regulatory documents and artwork used in regulatory documents.

Unit-V **8**

Clinical Trial Monitoring - Fundamentals of Clinical Monitoring, the processes and procedures of monitoring a clinical trial, Clinical, Pharmacological (including pharmacodynamics and pharmacokinetic) or adverse Effects with the objective of determining safety and efficacy of the new drug. Clinical Data Management And Biostatistics – establishment of protocol-specific data review and entry guidelines to document data validation and formatting procedures.

RBT-034: Bioprocess Economics and Project Management

L	T	P
3	0	0

UNIT I [8]

Introduction to statistical process control and capability analysis: Chance and assignable cause of quality variation, Statistical basis of process monitoring: control chart, choice of control charts, analysis of control chart, variable of control charts, X bar and R chart, Attribute control chart, Determining process and measurement capability

UNIT II [8]

DOE Approach to Medium Optimization: - traditional (linear) approach (OFAT) and multi-dimensional approach (Box-Bhenken Design, central composite design, Plackett-Burman Design, Downhill Method, Full factorial, Fractional factorial,);

UNIT III [8]

Introduction: Meaning, Nature and Scope of Economics, Meaning of Science, Engineering and Technology Managerial Economics and its scope in engineering perspective. Basic Concepts Demand Analysis, Law of Demand, Determinates of Demand, Elasticity of Demand-Price, and Income and cross Elasticity .Uses of concept of elasticity of demand in managerial decision

UNIT IV

[8]

Demand forecasting: Meaning, significance and methods of demand forecasting, production function, Laws of returns to scale & Law of diminishing returns scale. An overview of Short and Long run cost curves – fixed cost, variable cost, average cost, marginal cost, Opportunity cost.

UNIT V

[8]

Introduction: Concept, Development, application and scope of Industrial Management. Management Function: Principles Production requirements. Productivity: Definition, measurement, productivity index, types of production system, Industrial of Management- Management Tools – time and motion study, work simplification- process charts and flow diagrams, Production Planning, Specification of Ownership.

Text/Reference Books:

1. Douglas C Montgomery: Statistical Quality Control
2. Managerial Economics for Engineering: Prof. D.N. Kakkar
3. T.R. Banga: Industrial Engineering and Management
4. Managerial Economics: Maheshwari.
5. Khanna O.P.: Industrial Engineering

RBT-751: Environmental Biotechnology Lab

L	T	P
0	0	2

1. Study of laboratory equipments used in Environmental Biotechnology lab.
2. To perform the waste Water Sampling by Random Sampling Method
3. Preparation of stocks solutions.
4. Estimation of Biological Oxygen Demand (BOD) of waste water.
5. Estimation of Chemical Oxygen Demand (COD) of waste water.
6. Estimation of Dissolved Oxygen
7. Estimation of Total Hardness in given Water Sample.
8. Estimation of Total dissolved and suspended solid in waste water
9. Alkalinity& Acidity of waste water
10. Estimation of optimum dosage of ferric chloride for removal of suspended matter
11. Nitrogen estimation by Kjeldahl method,
12. To determine the amount of total Coliform in the water sample

RBT-752: Bioseparation & Down Stream Process Lab

L	T	P
0	0	2

1. Characteristics of Bioproducts: Flocculation and conditioning of broth
2. Mechanical separation: Filtration and Centrifugation
3. Cell disruption
4. Membrane based separation
5. Protein precipitation and its separation: Aqueous two phase extraction, Ultra filtration and Adsorption
6. Chromatography separation based on size, charge, hydrophobic interaction
7. Gel analysis/ assay for dialysed product
8. Product crystallization and drying

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**Study and Evaluation Scheme
B.TECH. BIO-TECHNOLOGY
(Effective from the session: 2019-20)**

4th Year, 8th Semester

S. No.	Subject Code	Subject Name	Teaching Deptt.	L-T-P	Th/Lab Marks	Sessional		Total	Credit
						ESE	CT TA		
1		Open Elective Course-II	Other Department	3-0-0	70	20	10	100	3
2	RBT-051-54	Departmental Elective-V	Core Department	3-1-0	70	20	10	100	4
3	RBT-061-064	Departmental Elective-VI	Core Department	3-0-0	70	20	10	100	3
4	RBT-851	Seminar	Core Department	0-0-3			100	100	2
5	RBT-852	Project-II	Core Department	0-0-12	350		250	600	12
	Total				560	60	380	1000	24

Departmental Elective-V

RBT-051: Integrated waste management for smart cities (NPTEL)

RBT-052: Tissue Engineering (NPTEL)

RBT-053: Novel Technologies for Food Processing and Shelf Life Extension

RBT-054: Industrial Biotechnology (NPTEL)

Departmental Elective-VI

RBT-061: Introductory mathematical models for biologists (NPTEL)

RBT-062: Medical Biomaterials (NPTEL)

RBT-063: Biostatistics & design of experiments (NPTEL)

RBT-064: Computer aided drug design (NPTEL)