

BIOTECHNOLOGY

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UNIVERSITY, UTTAR PRADESH, LUCKNOW



EVALUATION SCHEME & SYLLABUS

FOR

B. TECH. FOURTH (IV) YEAR

**BIOTECHNOLOGY**

AS PER

AICTE MODEL CURRICULUM

[Effective from the Session: 2021-22]

# BIOTECHNOLOGY

## B.Tech. VII Semester BIOTECHNOLOGY

SEMESTER- VII													
Sl. No.	Subject	Subject	Periods			Evaluation Scheme				End Semester		Total	Credit
	Codes		L	T	P	CT	TA	Total	PS	TE	PE		
1	KHU701/ KHU702	HSMC -1 #/ HSMC-2 #	3	0	0	30	20	50		100		150	3
2	KBT-071-074	Departmental Elective-IV	3	0	0	30	20	50		100		150	3
3	KBT-075-078	Departmental Elective-V	3	0	0	30	20	50		100		150	3
4		Open Elective-II	3	0	0	30	20	50		100		150	3
5	KBT751X	LAB-1	0	0	2				25		25	50	1
6	KBT752	Mini Project or Internship Assessment*	0	0	2				50			50	1
7	KBT753	Project I	0	0	8				150			150	4
8		MOOCs (Essential for Hons. Degree)											
		Total	12	0	12							850	18
*The Mini Project or internship (4 - 6 weeks) conducted during summer break after VI semester and will be assessed during VII semester.													
SEMESTER- VIII													
Sl. No.	Subject	Subject	Periods			Evaluation Scheme				End Semester		Total	Credit
	Codes		L	T	P	CT	TA	Total	PS	TE	PE		
1	KHU801/ KHU802	HSMC- 2#/HSMC-1#	3	0	0	30	20	50		100		150	3
2		Open Elective-III	3	0	0	30	20	50		100		150	3
3		Open Elective-IV	3	0	0	30	20	50		100		150	3
4	KBT851	Project II	0	0	18				100		300	400	9
5		MOOCs (Essential for Hons. Degree)	9	0	18								
		Total										850	18

## **B.TECH IV YEAR BIOTECHNOLOGY (DEPARTMENT ELECTIVE SUBJECTS)**

### **DEPARTMENTAL ELECTIVE- IV**

KBT071: Genomics and Proteomics

KBT072: Bioseparation and Downstream Processing

KBT073: Environmental Biotechnology

KBT074: Industrial Biotechnology

### **DEPARTMENTAL ELECTIVE- V**

KBT075: Biosafety, Bioethics, IPR & Patents

KBT076: Quality Control and Regulatory affairs

KBT077: Biomaterials

KBT078: Biostatistics & design of experiments

### **LAB (DEPARTMENTAL ELECTIVE)**

KBT751A: Genomics and Proteomic Lab

KBT751B: Bioseparation and Downstream Processing

KBT751C: Environmental Biotechnology Lab

KBT751D: Industrial Biotechnology Lab

# BIOTECHNOLOGY

## B.TECH IV YEAR VII SEMESTER BIOTECHNOLOGY

<b>SUBJECT CODE: KBT071</b>	<b>COURSE TITLE: Genomics &amp; Proteomics</b>
<b>EXAM DURATION: 3 HOURS</b>	<b>SEMESTER: VII (ODD)</b>
<b>L: T: P :: 3 : 0: 0 CREDIT: 3</b>	<b>PRE-REQUISITE: Molecular Biology &amp; Biochemistry</b>
<b>OBJECTIVE:</b> <ul style="list-style-type: none"><li>• Understand the structural principles governing the protein structures and their classifications.</li><li>• Identification of key motifs and domains in protein structures, and their interaction with ligands or substrates; DNA-protein interactions.</li><li>• Explain and distinguish various genomic features</li><li>• Explain molecular markers, various approaches for genetic and physical mapping of genomes; and also analyze recombinant frequency of molecular markers to create genetic maps</li></ul>	
<b>COURSE OUTCOME:</b> After completion of this course successfully, the students will be able to: <ul style="list-style-type: none"><li>• Acquire the knowledge for interactions of proteins and other macromolecules along with methods for their identification.</li><li>• Comprehend the basics of determination and prediction of three-dimensional structure of proteins.</li><li>• Describe various chemistries/platforms for Next-generation sequencing (NGS); and analyze NGS data to assemble genomes, annotate the assembly, and predict various kinds of variants.</li><li>• Identify genes/pathways/biological processes underlying a phenotype through differential gene expression analysis (using RNA-seq).</li></ul>	

### REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
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

# BIOTECHNOLOGY

## COURSE DETAIL: GENOMICS & PROTEOMICS

S N	CONTANT	LECTURE
I.	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	10
II.	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.	8
III.	Proteomics Protein analysis (includes measurement of concentration, amino-acid composition, N-terminal sequencing); 2-D electrophoresis of proteins; Microscale solution iso-electric focusing; Peptide fingerprinting; LC/MS-MS for identification of proteins and modified proteins; MALDITOF; SAGE and Differential display proteomics, Protein-protein interactions, Yeast two hybrid system.	8
IV.	Pharmacogenetics High throughput screening in genome for drug discovery-identification of gene targets, Pharmacogenetics and drug development.	6
V.	Functional genomics and proteomics Analysis of microarray data; Protein and peptide microarray-based technology; PCR-directed protein in situ arrays; Structural proteomics	8

# BIOTECHNOLOGY

<b>SUBJECT CODE: KBT072</b>	<b>COURSE TITLE: Bioseparation &amp; Down Stream Processing</b>
<b>EXAM DURATION: 3 HOURS</b>	<b>SEMESTER: VII (ODD)</b>
<b>L: T: P :: 3 : 0: 0      CREDITS: 3</b>	<b>PREREQUISITE: Knowledge of Molecular Techniques</b>
<b>OBJECTIVE:</b>	
<ul style="list-style-type: none"> <li>• The major objective of this course is to impart in students the skills to operate bioprocesses for production of various Bio-products</li> <li>• This course is formulated to teach various methods of product separation, isolation and purification To teach the construction of genomic c-DNA libraries, cloning and strain improvement</li> </ul>	
<b>COURSE OUTCOME:</b> After completion of the course the students will be able	
<ul style="list-style-type: none"> <li>• to operate, design and optimize the production medium, they will gain the ability to handle bioreactors to carry out different separation processes involving various types of bioproducts.</li> <li>• After completion of this course the students will be skilled in choosing a process of separation for a particular product, they will know how to design the relevant equipment, calculate the yield, and degree of purification.</li> </ul>	

### REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	Raja Ghosh, "Principles of Bioseparations Engineering", WorldScientific 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 DekkerInc.	1993
4.	Bailey & oils, Biochemical Engg. Fundamentals, McGraw-Hill	1990
5.	Roger G. Harrison, Paul Todd, Scott R. Rudge, Demetri P. Petrides, "Bioseparation science and Engineering" Oxford University press.	2003

# BIOTECHNOLOGY

## COURSE DETAILS: BIOSEPARATION & DOWNSTREAM PROCESSING

S N	CONTANT	LECTURE
I.	INTRODUCTION TO BIOSEPARATION PROCESS: 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.	8
II.	REMOVAL OF INSOUBLES: 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.	8
III.	ISOLATION OF PRODUCTS: 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.	8
IV.	PURIFICATION OF BIOPRODUCTS: 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.	8
V.	PRODUCT POLISHING: 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.	8

# BIOTECHNOLOGY

<b>SUBJECT CODE: KBT073</b>	<b>COURSE TITLE: Environmental Biotechnology</b>
<b>EXAM DURATION: 3 HOURS</b>	<b>SEMESTER: VII (ODD)</b>
<b>L: T: P: 3: 0: 0 CREDITS: 3</b>	<b>PREREQUISITE: Microbiology and Bioprocess Engineering</b>
<b>OBJECTIVE:</b> <ul style="list-style-type: none"> <li>• To teach basics of environment and its challenges in terms of pollution due to various activities</li> <li>• To develop understanding of biotechnology and microbiology in treating various kind of waste leading to production of various useful products</li> <li>• To impart knowledge of core engineering design in environmental waste treatment using biological processes</li> <li>• To develop mathematical and analytical skills required to design and operate system for source-based waste treatment</li> <li>• To impart knowledge in the area of regulatory framework and environmental compliance</li> </ul>	
<b>COURSE OUTCOME:</b> On successful completion of the course, the student will be able to: <ul style="list-style-type: none"> <li>• Distinguish the exact root cause of environmental pollution problems</li> <li>• Apply the biotechnology core principles in waste treatment system</li> <li>• Design the novel biological treatment system at institutional as well as industrial scale</li> <li>• Analyze the outcome of designed system based on mathematical analysis of result</li> <li>• Understand the regulatory mechanism in the area of environmental compliance laid down by various agencies</li> </ul>	

## REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	Waste Water Engineering Metcalf & Fuddy, 3rd ed.	2013
2.	Environmental Processes I-III, J. Winter, 2nd ed., Wiley Publications	2005
3.	Environmental Studies-Dwivedi & Mishra, Ed	2007
4.	Environmental Biotechnology B.C. Bhattacharya & Ritu Banerjee, Oxford Press	2007
5.	Essentials of Ecology & Environmental Science, S.V.S. Rana, Prentice-Hall India,	2006
6.	Perspectives in Environmental Studies, Anubha Kaushik & C P Kaushik,	2004
7.	Agarwal S.K. (1998), Environmental Biotechnology, APH Publishing Corporation, New Delhi	1998
8.	Environmental Sciences – Purohit, Shammi & Agrawal, New Age International Publishers, Student Edition	2004



# BIOTECHNOLOGY

## COURSE DETAILS: ENVIRONMENTAL BIOTECHNOLOGY

S N	CONTANT	LECTURE
I.	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.	10
II.	Biotechnology for waste treatment: Biological waste treatments and biofuel production. Microbiology of waste water treatments, Anaerobic digestion process for Methanogenesis: methanogenic, acetogenic, and fermentative microbe. Minimalnational standards for waste disposal.	8
III.	Engineering design and kinetics behavior analysis 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 batchreactor	8
IV.	Waste to wealth: bioconversion of agricultural and other highly organic waste materials into gainfully utilizable products – biogas, H <sub>2</sub> , celluloses and food and feed stocks. Bioremediation & Biomineralization: land, water, Contaminated Soil, industries, organic contaminants, heavy metals, Bioleaching of ores, Recovery of metals, Economical and social aspects of waste treatment.	6
V.	Environmental Impact Assessment: Relation between development and environment. Sustainable development and carrying capacity. Screening, scoping. Baseline studies and monitoring. Impact analysis. Public participation. Methodologies. Environmental Protection Act, 1986, Water Prevention and Control of Pollution Act, 1974, Water Prevention and Control of Pollution Cess Act, 1974, Air Prevention and Control of Pollution Act, 1981, Hazardous Wastes (Management and Handling) Rules. International environmental laws.	8

## BIOTECHNOLOGY

<b>SUBJECT CODE: KBT074</b>	<b>COURSE TITLE: Industrial Biotechnology</b>
<b>EXAM DURATION: 3 HOURS</b>	<b>SEMESTER : VII (ODD)</b>
<b>L: T: P :: 3:0:0 CREDITS: 3</b>	<b>PRE REQUISITES: Knowledge of Microbiology, Biochemistry</b>
<b>OBJECTIVE:</b> <ul style="list-style-type: none"> <li>• To provide the knowledge of Industrial Biotechnology.</li> <li>• To understand the use of living cells such as bacteria, yeast, algae or component of cells like enzymes, plants and animals to generate industrial products and processes.</li> <li>• To study techniques for genetic improvement of micro-organisms to improve yield of bioproducts.</li> <li>• To provide the knowledge of microbial production of pharmaceuticals.</li> <li>• To provide knowledge about biofuels.</li> </ul>	
<b>COURSE OUTCOME:</b> After successful completion of the course the students will be able to: <ul style="list-style-type: none"> <li>• Understand the role of industrial biotechnology in improving microbial cells as factories.</li> <li>• Understand the different types of bioreactors and the production aspects of commodity chemicals, pharmaceuticals and fine chemicals.</li> <li>• Apply knowledge of microorganisms in commercial production of flavours, fragrance, and microbial pigment in textile and industry.</li> <li>• Apply the process for commercial production of enzyme.</li> <li>• Understand the concept of biofuels and the process of Microbial Enhanced Oil Recovery and Microbial Leaching.</li> </ul>	

### REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	C. Vogel and C.L. Tadaro, Fermentation and Biochemical Engineering Handbook: Principles, Process, Design and Equipment, Noyes Publications	1996
2.	P.F. Stansbury and A. Whitaker, Principles of Fermentation Technology: An Introduction to Current Concepts, Pergamon Press	1993
3.	Glazer AN, Nikaido H : Microbial Biotechnology: Fundamentals of Applied Microbiology	2007
4.	Wulf Cruger and Anneliese Crueger, Biotechnology: A Textbook of Industrial Microbiology, Panima Publishing Corporation	2003
5.	Malden MA: Industrial Microbiology: An introduction; Blackwell Science	2001
6.	H.W. Blanch, S. Drew, D.I.C.Wang and M. Moo-Young, Comprehensive Biotechnology: The Practice of Biotechnology: Current Commodity Products, Pergamon Press.	1985

# BIOTECHNOLOGY

## COURSE DETAILS: INDUSTRIAL BIOTECHNOLOGY

S N	CONTANT	LECTURE
I.	<b>Introduction to Industrial Biotechnology:</b> Overview of fermentation and other industries with their commercial products employing the use of microorganisms; strain improvement through mutation and recombination in industrial microorganisms, Integrated Strain improvement program (Precision Engineering Technology), biosynthetic technology.	8
II.	<b>Microbes in agriculture and food industry:</b> beneficial soil microorganisms, biofertilizers and biopesticides, SCP, microbial production of wine, beer and vinegar; biopreservatives (Nisin), cheese, biopolymers (xanthan gum, PHB etc), vitamins; Bioflavours and biopigments; microbial production of flavours and fragrances; microbial pigments in textile and food industry.	8
III.	<b>Bioreactors, Production of cell biomass, primary metabolites and enzymes:</b> Different type of Bioreactors and Bioreactor design, Production of ethanol, acetone, butanol, citric acid, dextran and amino acids, Production of industrial enzymes such as proteases, amylases, lipases, cellulases, whole cell biocatalysis, Applications of bioconversion, transformation of steroids and sterols.	8
IV.	<b>Microbial production of pharmaceuticals and other bioproducts:</b> Antibiotics, enzyme inhibitors and specialty chemicals; production of Vitamin E, K, B2 and B12, glutamic acid, L-Lysine. Transformation of non-steroidal compounds, antibiotics, genetic engineering of microorganisms for production of nonribosomal peptides (NRPS) and polyketides (PKS), anticancer drugs.	8
V.	<b>Bioenergy</b> -fuel from biomass, production and economics of biofuels, biogas, bio-refineries, Microbial Enhanced Oil Recovery (MEOR).	8

## BIOTECHNOLOGY

<b>SUBJECT CODE: KBT-075</b>	<b>COURSE TITLE: Biosafety, Bioethics, IPR &amp; Patents</b>
<b>EXAM DURATION: 3 HOURS</b>	<b>SEMESTER : VII (ODD)</b>
<b>L: T: P :: 3:0:0 CREDITS: 3</b>	<b>PRE REQUISITES: Basic biology, GMO's and bioethics.</b>
<b>OBJECTIVE:</b> <ul style="list-style-type: none"> <li>• To learn about the IPR and its legal provisions and to know about the significance of biosafety in different system.</li> <li>• To learn about concepts of Patent, Copyright, Trademarks and related IP</li> <li>• To learn about patent system, biosafety regulatory framework and basics of bioethics</li> </ul>	
<b>COURSE OUTCOME:</b> After successful completion of the course the students will be able to: <ul style="list-style-type: none"> <li>• Get an adequate knowledge on biosafety-regulatory framework for GMO's in India</li> <li>• Understand biosafety-regulatory framework for GMOS at international level</li> <li>• Identify the role bioethics in IPR</li> <li>• Disseminate knowledge on different tools of IPR o make students aware about current trends in IPRand Govt. supports in promoting IPR</li> <li>• Identify the role of Patent and Patent law</li> </ul>	

### REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	Beier, F.K., Crespi, R.S. and Straus, T. Biotechnology and Patent protection- Oxford and IBH Publishing Co. New Delhi.	2007
2.	Intellectual property rights and Bio-Technology (Biosafety and Bioethics), Anupam Singh, Ashwani Singh, NPH, New Delhi	2012
3.	Sasson A, Biotechnologies and Development, UNESCO Publications..	1988
4.	Regulatory Framework for GMOs in India, Ministry of Environment and Forest, Government of India, New Delhi	2006
5.	Cartagena Protocol on Biosafety , Ministry of Environment and Forest, Government of India, New Delhi	2006

# BIOTECHNOLOGY

## COURSE DETAILS: BIOSAFETY, BIOETHICS, IPR & PATENTS

S N	CONTANT	LECTURE
I.	<p><b>BIOSAFETY-REGULATORY FRAMEWORK FOR GMOS IN INDIA</b>                      Regulatory framework in India governing GMOs-Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committee (IBC), Review Committee on Genetic Manipulation, Genetic Engineering Approval Committee (GEAC), State Biosafety Coordination Committee (SBCC), District Level Committee (DLC). Recombinant DNA Guidelines (1990), Revised Guidelines for Research in Transgenic Plants (1998), Seed Policy (2002), Prevention Food Adulteration Act (1955), The Food Safety and Standards Bill (2005), Plant Quarantine Order (2003), Regulation for Import of GM Products Under Foreign Trade Policy (2006-2007), National Environment Policy (2006). Rules for the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells (Ministry of Environment and Forests Notification, (1989)</p>	8
II.	<p><b>BIOSAFETY-REGULATORY FRAMEWORK FOR GMOS AT INTERNATIONAL LEVEL</b>                      Convention of Biological Diversity (1992) – Cartagena Protocol on Biosafety – Objectives and salient features of Cartagena Protocol – Advanced Information Agreement (AIA) procedure – procedures for GMOs intended for direct use-risk assessment-risk management-handling, transport, packaging and identification of GMOs-Biosafety Clearing House-unintentional transboundary movement of GMOs-Benefits of becoming a party to the Cartagena Protocol- status of implementation in India.</p>	8
III.	<p><b>BIOETHICS</b> Distinction among various forms of IPR, ,Prior art for a patent, Patenting live microorganism, Human Genome project and ethical issues, Animal cloning, human cloning and their ethical issues, Experimenting on animals. Public education of producing transgenic organism, legal and socioeconomic impacts of biotechnology, testing drugs on human volunteers, Hazardous materials used in biotechnology, their handling and disposal.</p>	8
IV.	<p><b>INTELLECTUAL PROPERTY RIGHTS</b> Concept of property, rights, duties and Jurisprudential definition, Introduction to patent, copy right, trademarks, Design, geographical indication. History and evolution of IPR, Economic importance of IPR, Indian patent act 1970 (amendment 2000), Distinction among various forms of IPR, invention step, biopiracy and bioprospecting-Appropriate case studies. Infringement/violation of patent, remedies against infringement (civil, criminal, administrative)</p>	8
V.	<p><b>PATENTS AND PATENT LAWS</b> Plant and Animal growers rights patents trade secrets, and plant genetic recourses GATT and TRIPS, Dunkels Draft Patenting of biological materials, Current Issues of Patents for higher animal and higher plants, patenting of transgenic organisms, isolated genes and DNA sequences..</p>	8

## BIOTECHNOLOGY

<b>SUBJECT CODE: KBT076</b>	<b>COURSE TITLE: Quality Control &amp; Regulatory affairs</b>
<b>EXAM DURATION: 3 HOURS</b>	<b>SEMESTER: VII (ODD)</b>
<b>L: T: P :: 3 :0: 0      CREDIT: 3</b>	<b>PRE-REQUISITE: IPR &amp; Industrial Management</b>
<b>OBJECTIVE:</b> <ul style="list-style-type: none"> <li>• This course is designed with an objective to provide an understanding of the knowledge of Quality control and Quality management</li> <li>• To learn the concepts of GMP, GLP, standard test procedure and CPCSEA guidelines in Biological samples</li> <li>• To provide the knowledge of Quality review and batch release document, audits of quality control etc.</li> <li>• To develop understanding of Good documentation processes, clinical studies guidelines, IP generation pharmacovigilance and product registration guidelines etc.</li> </ul>	
<b>COURSE OUTCOME:</b> After completion of this course successfully, the students will be able to: <ul style="list-style-type: none"> <li>• Understand basic concept of QC and Quality management</li> <li>• Explain GLP, GMP, Standard Operating Process and CPCSEA guidelines</li> <li>• Understand of the quality review and audits of QC practices</li> <li>• Explain the clinical studies guidelines, Good documentation practices, IPR and product Registration guidelines etc.</li> </ul>	

### REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	Sharp J. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance. CRC Press	2005
2.	Haider SI. Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance. St. Lucie Press	2002
3.	Swarbrick J. Encyclopedia of Pharmaceutical Technology. Informa Healthcare	2007
4.	Kolman J, Meng P, Scott G. Good Clinical Practice: Standard Operating Procedures for Clinical Researchers. Wiley	1998
5.	Signore AA, Jacobs T. Good Design Practices for GMP Pharmaceutical Facilities. Taylor & Francis Group	2005

# BIOTECHNOLOGY

## COURSE DETAILS: QUALITY CONTROL AND REGULATORY AFFAIRS

S N	CONTANT	LECTURE
I.	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.	8
II.	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.	8
III.	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	8
IV.	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.	8
V.	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.	8

## BIOTECHNOLOGY

<b>SUBJECT CODE: KBT077</b>	<b>COURSE TITLE: Biomaterials</b>
<b>EXAM DURATION: 3 HOURS</b>	<b>SEMESTER: VII (ODD)</b>
<b>L: T: P :: 3 : 0: 0 CREDITS: 3</b>	<b>PREREQUISITE: Knowledge Of Chemistry, Biochemistry, Molecular Biology</b>
<p><b>OBJECTIVE:</b></p> <ul style="list-style-type: none"> <li>• This course is designed with an objective to provide an understanding of the basic concepts and properties required for a material to be biocompatible.</li> <li>• To learn about testing &amp; quality assessment of the biomaterials.</li> <li>• Students will get exposure to latest biomaterials and their application in the area of biomedical.</li> </ul>	
<p><b>COURSE OUTCOME:</b> After successful completion of the course the students will be able to:</p> <ul style="list-style-type: none"> <li>• Differentiate whether a material has the compatibility with biological system to be used for applications.</li> <li>• To assess the quality of biomaterials,</li> <li>• To design aspects of new biomaterials or modify existing material for enhancement of biocompatibility.</li> </ul>	

### REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	Biomaterials: An Introduction by Park J.B. and Lakes R.S., Plenum Press, New York	2007
2.	Biomaterials, Medical Devices & Tissue Engineering: An Integrated Approach by Silver F.H., Chapman and Hall publication.	1994
3.	Biomaterials science: an introduction to materials in medicine by Buddy D. Ratner., Elsevier Academic Press	2012
4.	Biomaterials: A Tantalus Experience by Jozef A. Helsen., Yannis Missirlis Springer	2010
5.	Biomaterials by Temenoff Johnna S., Dorling Kindersley India Pvt Ltd.	2007



# BIOTECHNOLOGY

## COURSE DETAILS: Biomaterials

S N	CONTANT	LECTURE
I.	Introduction and overview of biomaterials: Definition of biomaterials – biologically derived materials or materials compatible with biology. Biomaterials: Classification of bio-materials (based on tissue response), Tissue engineering, Biosensor.	8
II.	Interactions of materials: Interactions of materials with human body, bio-compatibility of materials, metals (stainless steels, cobalt-chromium alloys, titanium based alloys, nitinol), Ceramics (carmons, alumina, resorbable ceramics, surface reactive ceremics), bio polymers(collagens, elastin, mucopolysachharides, cellulose and derivatives, chitin and other polysaccharides and composites as biomaterials.	8
III.	Biomaterials for human use :Metallic biomaterials as implants, Bioceramics and ceramic biomaterials, Polymeric biomaterials – classification, natural and synthetic materials; biomedical applications, Composite biomaterials – classification, biological responses to composite biomaterials, biomedical applications..	8
IV.	Quality and Testing of Biomaterials Degradation, Corrosion, Deformation, Fracture, Brittle to ductile transition, Fatigue, Tribology. Recent developments in biomaterials, legal issues related to development of biomaterials	8
V.	Nanobiomaterials : Definition and classes of nanobiomaterials Polymeric, ceramic and composite nanobiomaterials Scaffolding, tissue engineering (including stem cells), growth factor delivery with nanobiomaterials	8

# BIOTECHNOLOGY

<b>SUBJECT CODE: KBT078</b>	<b>COURSE TITLE: Biostatistics &amp; design of experiments</b>
<b>EXAM DURATION: 3 HOURS</b>	<b>SEMESTER: VII (ODD)</b>
<b>L: T: P :: 3 : 0: 0      CREDIT: 3</b>	<b>PRE-REQUISITE: Mathematics</b>
<b>OBJECTIVE:</b> This course is designed with an objective to provide an understanding of the knowledge of Biostatistics to students so that they can apply statistics in defining the type and quantity of data need to be collected as well as organizing and summarizing the data. This course will also be helpful to analyzing the data, drawing conclusions, and assessing the strengths of the conclusions and evaluating their uncertainty.	
<b>COURSE OUTCOME:</b> After completion of this course successfully, the students will be able to: <ul style="list-style-type: none"><li>• Understand basic concept of handling univariate, bivariate, correlation &amp; regression</li><li>• Explain probability, variance and theoretical distribution etc. Understand sampling , statistical quality control and data analysis</li><li>• Explain design of experiment and process control</li></ul>	

## REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	S.C.Gupta & V.K.Kapoor, Fundamentals of Mathematical Statistics, Sultan Chand and Sons, New Delhi ,	2003
2.	W.Ewans & G.Grant, Statistical Methods in Bio informatics – An Introduction. Springer	2005
3.	Chap T. Le and Lynn E. Eberly, Introductory Biostatistics, Wiley	2016

# BIOTECHNOLOGY

## COURSE DETAILS: BIOSTATISTICS & DESIGN OF EXPERIMENTS

S N	CONTANT	LECTURE
I.	Introduction to bio-statistics, Handling univariate and bivariate data – Measures of central tendency – Measures of dispersion –Skewness & Kurtosis – Correlation and Regression.	8
II.	Probability concepts, conditional probability, Baye's theorem, one – dimensional random variables, expectation, variance, moments. Theoretical distributions: Binomial, Poisson, Normal (Problems only).	8
III.	Sampling, Testing of Hypothesis and Statistical Quality Control: Introduction , Sampling Theory (Small and Large) , Hypothesis, Null hypothesis, Alternative hypothesis, Testing a Hypothesis, Level of significance, Confidence limits, Test of significance of difference of means, T-test, F-test and Chi-square test.	8
IV.	The Analysis of Variance: Concept – Assumptions-One way classification and two-way classifications. Designing Engineering Experiment: Concept of Randomization, Replication and local control - Completely Randomized Design -Randomized Block Design –Latin square Design.	8
V.	Basic concepts of statistical quality control. Process control – control charts for variables - $\bar{X}$ and R, $\bar{X}$ and s charts control charts for attributes : p chart, np chart, c chart.	8

<b>SUBJECT CODE: KBT751A</b>	<b>COURSE TITLE: Genomics &amp; Proteomics Lab</b>
<b>EXAM DURATION: 2 HOURS</b>	<b>SEMESTER: VII (ODD)</b>
<b>L: T: P :: 0 : 0 : 2      CREDIT: 1</b>	<b>PRE-REQUISITE: Molecular Biology &amp; Biochemistry</b>
<b>OBJECTIVE:</b>	
<ul style="list-style-type: none"> <li>• To isolate genetic materials from bacterial cells</li> <li>• To determine and characterization of enzyme kinetics</li> </ul>	
<b>COURSE OUTCOME:</b> After completion of this course successfully, the students will be able to:	
<ul style="list-style-type: none"> <li>• Express and purify recombinant protein in bacterial system</li> <li>• Characterized purified protein through enzymatic activity and kinetics</li> <li>• Work with publically available genome sequencing data</li> <li>• Perform genomic DNA and RNA isolation from bacteria and independently setup qRT-PCR</li> </ul>	

**REFERENCE BOOKS:**

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	Application of DNA microarrays in Biology	2005
2.	Functional Proteomics	2005
3.	Proteomic to study genes and genomes	2000

**COURSE DETAILS: GENOMICS & PROTEOMICS LAB**

S N	LIST OF EXPERIMENTS
1.	Expression of heterologous protein in bacterial system.
2.	Detection of expressed protein.
3.	Purification of recombinant protein.
4.	Characterization of purified protein using enzymatic activity.
5.	Determination of kinetic parameters.
6.	Browsing through various publically available genome databases, retrieving and working with genome data. KEGG genomes, retrieval of genes, proteins and intergenic regions.
7.	Genomic DNA isolation from bacterial strains and estimation of DNA concentration using Nanodrop, agarose gel electrophoresis.
8.	RNA isolation from Synechocystis and quality check (RIN number) using Bioanalyser chip, cDNA synthesis and qRT-PCR analysis.
9.	Demonstration of Agilent's microarray scanner and DNA microarray protocol.
10.	Raw data processing, scatter plots, global normalization of data, fold changes and finding differentially expressed genes.

## BIOTECHNOLOGY

<b>SUBJECT CODE: KBT751B</b>	<b>COURSE TITLE: Bioseparation &amp; Downstream Processing Lab</b>
<b>EXAM DURATION: 2 HOURS</b>	<b>SEMESTER: VII (ODD)</b>
<b>L: T: P :: 0 : 0 : 2 CREDIT: 1</b>	<b>PRE-REQUISITE: Basic Knowledge of molecular biology Techniques</b>
<b>OBJECTIVE:</b> <ul style="list-style-type: none"> <li>• To isolate the various bioproducts.</li> <li>• To develop understanding of bioseparation</li> <li>• To provide practical knowledge of purification of target bioproducts</li> </ul>	
<b>COURSE OUTCOME:</b> On successful completion of the course, the student will be able to: <ul style="list-style-type: none"> <li>• Understand and explain the bio-separation principles involved in purification of bio-products.</li> <li>• Evaluate concepts selection of membranes and assess the results of protein purification.</li> <li>• Design the method for bio-separation of proteins.</li> <li>• Recover and subsequent purification of target bioproducts.</li> </ul>	

### REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	J. Jayaraman, "Laboratory Manual in Biochemistry", 1st Edition, New Age International.	1993
2.	Keith Wilson and John Walker, Practical Biochemistry—Principles and Techniques, Cambridge, 5th Ed.	2000

### COURSE DETAILS: BIOSEPARATION & DOWNSTREAM PROCESSING LAB

S N	LIST OF EXPERIMENTS
1.	Characteristics of Bioproducts: Flocculation and conditioning of broth
2.	Mechanical separation: Filtration and Centrifugation
3.	Determination of volumetric mass transfer coefficient ( $k_L a$ )
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 dialyzed product
8.	Product crystallization and drying
9.	Estimation of Alcohol Content in Wine by Dichromate Oxidation followed by Redox Titration Chemical Concepts and Techniques
10.	Product preservative methods -chemical, physical and natural

<b>SUBJECT CODE: KBT753C</b>	<b>COURSE TITLE: Environmental Biotechnology Lab</b>
<b>EXAM DURATION: 2 HOURS</b>	<b>SEMESTER: VII (ODD)</b>
<b>L: T: P :: 0 : 0: 2      CREDIT: 1</b>	<b>PRE-REQUISITE: Basic knowledge of Microbiology and Bioprocess engineering</b>
<b>OBJECTIVE:</b>	
<ul style="list-style-type: none"> <li>• Hands on experience on water &amp; soil treatments using environmental friendly methods.</li> <li>• This course is designed to give the students hands-on experience regarding monitoring of environmental parameters as part of field studies</li> </ul>	
<b>COURSE OUTCOME:</b> On successful completion of the course, the student will be able to	
<ul style="list-style-type: none"> <li>• Learn about various environment friendly methods for Environmental Biotechnology.</li> <li>• Identify and appreciate the parameters for assessing environment.</li> </ul>	

**REFERENCE BOOKS:**

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	Hurst, C.J., Crawford, R.L., Knudsen, G.R., MacInerney, M.J. and Stetzenbach, L.D., "Manual of Environmental Microbiology", 2nd Ed., ASM press	2002

**COURSE DETAILS: ENVIRONMENTAL BIOTECHNOLOGY LAB**

S N	LIST OF EXPERIMENTS
1.	Isolation, Identification, characterization of microbes collected from nearby polluted area/ industries and study of their enzymes.
2.	Environmental influence and control of microbial growth.
3.	Microbial degradation of textile dyes/pesticides/hydrocarbons and oils
4.	To determine BOD value for determining biodegradability of solution
5.	To determine COD value for determining organic strength of solution (Closed Reflux Method)
6.	Determination of metals in waste water and their removal.
7.	Effluent treatment plant (ETP): Primary, chemical and biological treatment
8.	Soil Quality analysis.
9.	Water Quality analysis
10.	Field Trip : (A) Wastewater Treatment Plant (B) How the community deals with domestic solid waste (Collection, disposal and treatment)

# BIOTECHNOLOGY

<b>SUBJECT CODE: KBT751D</b>	<b>COURSE TITLE: Industrial Biotechnology Lab</b>
<b>EXAM DURATION: 2 HOURS</b>	<b>SEMESTER : VII (ODD)</b>
<b>L: T: P :: 0:0:2 CREDITS: 1</b>	<b>PRE REQUISITES: Knowledge of Microbiology, Biochemistry</b>
<b>OBJECTIVE:</b> <ul style="list-style-type: none"> <li>• To produce various bioproducts from cells and tissues.</li> <li>• To isolate the industrially important microorganisms.</li> <li>• To study techniques for isolation and purification of bioproducts.</li> <li>• To provide the knowledge about determining the various important characteristic of industrially important enzymes.</li> </ul>	
<b>COURSE OUTCOME:</b> After successful completion of the course the students will be able to: <ul style="list-style-type: none"> <li>• Demonstrate the production of bioproducts like amylase and citric acid and ethanol.</li> <li>• Isolate the amylolytic microorganism.</li> <li>• Purify the industrially important enzymes and proteins.</li> <li>• Can perform the enzymatic assay.</li> </ul>	

## REFERENCE BOOKS:

S.N	NAME OF AUTHORS/BOOKS/PUBLISHERS	YEAR OF PUBLICATION
1.	Glazer AN, Nikaido H : Microbial Biotechnology: Fundamentals of Applied Microbiology Eisenthal, R. & Danson N.J. (Eds) Enzyme Assays: "A Practical Approach", IRI Press, Oxford, UK	1992
2.	Industrial Biotechnology: Products and Processes	2016
3.	Laboratory Manual In Industrial Biotechnology By P. Chellapandi	2007
4.	Practical Manual on Fermentation Technology by S. Kulandaivelu, S. Janarthanan	2012

## COURSE DETAILS: INDUSTRIAL BIOTECHNOLOGY LAB

S N	LIST OF EXPERIMENTS
1.	Production and partial purification of Amylase in shake flask culture.
2.	Isolation of amylolytic microorganisms.
3.	Production of Citric acid using Aspergillus species.
4.	Protein precipitation and membrane based separation using dialysis.
5.	Purification of Enzyme by ammonium sulphate fractionation.
6.	Comparative studies of ethanol production using different substrates.
7.	Determination of cellulolytic activity by DNS method.
8.	Enzyme assay; activity and specific activity determination of amylase.