

Maharashtra Education Society's **Abasaheb Garware College**(Autonomous)

(Affiliated to Savitribai Phule Pune University)

Two Year Master's Program in Biotechnology (Faculty of Science and Technology)

Syllabi under Autonomy M.Sc. I (Biotechnology)

Choice Based Credit System Syllabus

To be implemented from Academic Year 2022-2023

M.Sc. (Biotechnology)

Preamble

Biotechnology is a field that combines basics of life science (biology) and technology. It has been one of the most fast-growing fields in last few decades. The realm of Biotechnology involves understanding and application of basic sciences such as Physics, Chemistry, Mathematics as well as applied sciences such as Microbiology, Food technology, Bioinformatics, Recombinant DNA technology. State of the art technologies such as Artificial Intelligence and Machine learning are now being explored for their application in Biotechnology. Biotechnology is one such course that provides an educational environment where STEM- Science Technology Engineering and Mathematics are not only taught but practised together. India has recently implemented its NEP2020- New educational policy. One of the major objectives of NEP is to bridge gaps in education and industry by empowering the students by providing them with training in skill-based courses. To provide such training there is a need to develop courses/syllabi with subjects which provide knowledge about the current and most relevant technologies. This syllabus includes an amalgamation of theory as Practicals of classical subjects such as Cell Biology, Molecular Biology, Genetics, Molecular Biology and Advanced subjects such as Genomics, Proteomics, Bioinformatics, Nanobiotechnology and Genetic Engineering. Along with the training of basics of core subject the students need to be exposed to subjects such as entrepreneurship and intellectual property rights to inculcate interest in product development. Subjects such as Clinical Database management, Bioethics, Biosafety Pharmaceutical Biotechnology & Drug Designing have been critically curated to prepare students for Industry jobs. Environment Biotechnology, Agriculture Biotechnology and Food Biotechnology subject syllabi have been designed in order to expose students to state-of-the art techniques used in these fields. The proposed credit-based curriculum ensures the requirement of academia and industry. Theory supplemented with extensive practical skillsets will help a graduate student to avail the opportunities in the applied fields (research, industry or institutions) without any additional training. benefit of society and sustainable development.

Programme Outcomes:

- 1. To impart advanced knowledge in life sciences and cutting-edge technologies
- To equip students with skill sets to provide academic and professional excellence
- 3. To inculcate interdisciplinary research aptitude in students
- 4. To encourage independent thinking, develop analytical ability through research project
- 5. To inculcate scientific, social and environmental awareness in students

Eligibility:

Bachelor of Science in Biotechnology, B.Sc. Blended, B.Sc. with Vocational Biotechnology and B.Sc. (with Biotechnology, as one of the principal subjects) with 55% marks as minimum for general category and 50% marks as minimum for reserved category students.

Structure of the Course: M.Sc. Biotechnology

Year	Semester	Course Type	Course Code	Course Title	Remark	Credit	No. of Lectures /Practical to be conducted
			PSBT-111	Biological Chemistry	Т	4	60
		Core	PSBT-112A	Cell Biology	Т	2	30
		Compulsory Theory	PSBT-112B	Molecular Biology	Т	2	30
		Papers	PSBT-113A	Genetics	T	2	30
	I		PSBT-113B	Immunology	Т	2	30
		Core Practical Paper	PSBTP-114	Laboratory Course I - Biological Chemistry, Cell, Molecular Biology, Immunology and Genetics	P	4	30
1		Choice Based Optional	PSBTELE- 115A PSBTELEP- 115A	Environmental Biotechnology Practicals in Environmental Biotechnology	Choose any one of the	2T 2P	30 15
		Papers	PSBTELE- 115B PSBTELEP- 115B	Food Biotechnology Food Biotechnology	optional papers	2T 2P	30 15
	Sem	ester II					

		Core	PSBT-121	Genetic Engineering	Т	4	60
	II	Compulsory Theory	PSBT-122	Bacteriology and Virology	Т	4	60
		Papers	PSBT-123	Plant Biotechnology	Т	4	60
		Core Practical Paper	PSBTP-124	Laboratory Course II - Genetic Engineering, Bacteriology and Virology, Plant Biotechnology	P	4	30
		Choice Based Optional	PSBTELE- 125A	Clinical Research, Data Base management, & IPR	Choose any one of the optional	4	60
		Papers	PSBTELE- 125B	Medical Biotechnology	papers	4	60
	III	Core Compulsory Theory Papers	PSBT-231	Animal and Stem Cell Technology	Т	4	60
			PSBT-232	Bioprocess engineering	Т	4	60
			PSBT-233	Bioinformatics & Biostatistics	Т	4	60
2		Core Practical Paper	PSBTP-234	Laboratory Course III- Animal Biotechnology, Bioprocess engineering, Bioinformatics & Biostatistics	P	4	30
		Choice Based Optional Papers	PSBTELE- 235A PSBTELEP- 235A	Nano Biotechnology Nano Biotechnology	Choose any one of the optional papers	2T 2P	30 15

			PSBTELE- 235B	Agricultural Biotechnology		2T	30
			PSBTELEP- 235B	Agricultural Biotechnology		2P	15
		Core	PSBT-241A			2	30
	IV	Compulsory Theory Papers		Genomics	Т		
			PSBT-241B	Proteomics	T	2	30
2			PSBT-242	Advanced Bio analytical Techniques	Т	4	60
2		Core Practical Paper	PSBTP-243	Research Project	P	4	
		Choice Based Optional Papers	PSBTELE- 244A	Bio entrepreneurship & Start up Designing		4	60
			PSBTELE- 244B	Pharmaceutical Biotechnology & Drug Designing	Choose any two of the	4	60
			PSBTELE- 244C	Research Methodology & Scientific Communication	optional theory papers	4	60
			PSBTELE- 244D	Quality Control, Bio safety & Bioethics		4	60
		Total Credits		1		80	

Semester I

Course Code and title: PSBT-111 Biological Chemistry

Credits: 04 **Total Lectures: 60**

Course Outcomes:

1. To understand protein biochemistry, secondary metabolites and how their functions are governed by their structures.

2. To help students to understand the applications of enzymes and secondary metabolites in the biological field.

Units	Topics	Number
		of
		Lectures
1	Overview of Protein Structure, Protein Chemistry : Structure of	
	Proteins: Primary, Secondary, Tertiary, quaternary. Ramachandran	
	plot Study of protein motifs and protein families. Specific protein	
	structures in details- Keratin, Collagen, Myoglobin and	
	Haemoglobin. Include Introduction to Protein Sequencing, Edman	
	Degradation	
	• Protein folding mechanisms and Pathways, Factors affecting	
	stability- Molten globule, energy funnel, chaperons.	
	• Protein misfolding and disease- Sickle cell anaemia, Crohn's	
	Disease, Prion diseases	
	•Protein –protein interaction (immune system and	
	immunoglobulin's) and protein –DNA interaction (DNA binding	
	motifs- helix-turn-helix, leucine zipper, zinc finger, helix-loop-helix	
	and interaction with drugs)	
	• Structure –function relationship	
	Protein Engineering and its applications	
	Peptides and Therapeutic Proteins, Protein Interactions	
	Modulated by Chemical Energy: Actin, Myosin, and Molecular	
	Motors	20
2	Enzymes	
	Overview of Enzymes structure and function– Concept of active	
	site, binding sites, Stereospecificity of enzyme and ES complex	
	formation.	
	Multienzyme complexes	
	• Enzyme Activity- Various factors influencing enzyme activity and	
	enzyme inhibition Mechanism of enzyme action and Enzyme	4.0
	regulation.	10

Mich	me kinetics- Rate of reactions, steady state enzyme kinetics,	
in en	aelis-Menten Equation - form and derivation. Significance of and Km, K/cat. Bisubstrate reactions. Graphical procedures zymology. Lineweaver Burke's Plot, Ediee Hofstee plot, 's Plot	
• Clinio	al and Industrial Applications of enzymes: Diagnostics and	
thera	peutic enzymes used in a Biosensors (glucose oxidase,	
Chole	esterol Oxidase),	
• Enzy	me Engineering	
3 Metal	polomics:	
• Ove	view of metabolism, Integration of Metabolism	
	Metabolome – Metabolic flux, Metabolic flux analysis	
	abolic engineering – 2 eg. Polyketides Synthesis, Xenobiotics	10
	chemistry	
• Intro acids Carbo Intro precu • Path 1. Mee 2.Shil 3.Isop • Stud 1. Alk 2. Phe	duction to classes of naturally occurring compounds: Fatty, Alkaloids, Terpenoids, Steroids, Flavonoids, Anthocyanins, Ohydrates, Complex compounds, Essential oils luction to secondary Metabolism, primary metabolite as rsors of secondary Metabolite ways for secondary Metabolite valonate pathways timate Pathway (IPP) by of secondary Metabolite	
	•	
	ction methods – Physical and chemical	
	raction of Phytochemicals: Maceration, Soxhlet extraction, distillation, Hydrodistillation, Wax extraction, Fractional	
	llization, Fractional distillation, Spinning band distillation	
etc.	,	
	llysis of Crude Extracts and Pure Phytochemicals: Physical	
	ods, Elemental analysis, Chromatographic Techniques,	
	ral methods	20

- 1. Proteins: Biotechnology and Biochemistry, (2001),1st edition, Gary Walsch, Wiley, USA
- 2. Pharmacognosy, (2008), 14th edition, Dr. C. K. Kokate, A. P. Purohit, S. B. Gokhale, Nirali Prakashan, India.

- 3. Trease and Evans' Pharmacognosy, (2009), 16th edition, William Charles Evans, Saunders Ltd. USA.
- 4. Metabolic Engineering: Principles and Methodologies. (1998). Gregory N Stephanopoulos, Aristos A Aristidou, Jens Nielsen. Publisher: Academic Press, San Diego, US
- 5. Fundamentals of Biochemistry. (2008), 3rd Edition, Donald Voet & Judith Voet, John Wiley and Sons, Inc. USA
- 6.Lehninger, Principles of Biochemistry. (2021), 8th Edition David Nelson& Michael Cox and Aaron Hoskins, MacMillan International, NY.
- 7. Biochemistry: (2012), 7th Edition, Jeremy Berg, Lubert Stryer, W.H. Freeman and company, NY
- 8. Nucleic acids in Chemistry and Biology; (2022), 4th Edition, G. M. Blackburn, Martin Egil, Michael J Gait, Jonathan k Watts, RSC Publication, UK.

Course Code and title: PSBT-112A Cell Biology

Credits: 02 **Total Lectures: 30**

Course outcome:

1. To understand molecular mechanisms of intracellular transport, cell communication and cell signaling,

2. To introduce students to mechanisms of cell death, cell differentiation and cancer

Units	Topics	Number
		of
		Lectures
1	Cell structure and transport across membranes	
	• Specialized Cells: Muscle & Nerve cells, Structure & functions	
	•Molecular basis of muscle contraction.	
	•Mechanism of nerve transmission- Resting and action potential,	
	electrical and chemical transmission, Neurotransmitters and their receptors.	
	•Plasma membrane types (animal, plant and bacterial)	
	•Transport across plasma membrane and intra-cellular transport	
	(vesicular and membrane transport) at molecular level	
	Organelles and membrane trafficking	
		10
2	Cell communication: • Extracellular matrix and cell junctions-	
	relevance to tissue structure and function	
	• Cell signalling: communication between cells and environment	
	•Signalling at cell surface, signalling molecules, hormones and	
	receptors Signalling nothways that control gone activity signal transduction	
	•Signalling pathways that control gene activity, signal transduction	10
3	and second messengers Cell Differentiation, Cell Cycle, Cell Death, Cell transformation:	10
3	•Cell differentiation in plants and animals	
	Cell division: An over view of mechanics of Cell Division	
	Assembly and disassembly of cytoskeletal elements, role in cell	
	division	
	•Cell cycle and its regulation- Cyclins, Cyclin dependent kinases,	
	inhibitors.	
	•Cell death- Role of hormones and growth factors, Programmed	
	cell death in plants and animals	
	•Cell transformation and etiology of cancer	10

- 1. Molecular Cell Biology. (2012) 7th Edition, Lodish H., Berk A, Kaiser C., KReiger M., Bretscher A., Ploegh H., Angelika Amon A., Matthew P. Scott M.P., W.H. Freeman and Co., USA
- 2. Molecular Biology of the Cell, (2007) 5th Edition Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, Peter Walter. Garland Science,
- 3. Cell Biology, (2010) 6th edition, Gerald Karp. John Wiley & Sons., USA
- 4. The Cell: A Molecular Approach, (2013), 6th edition Geoffrey M. Cooper, Robert E. Hausman, Sinauer Associates, Inc. USA

Course Code and title: PSBT-112B Molecular Biology

Credits:02 **Total Lectures: 30**

- 1. To understand concept of genome and its organization
- 2. To learn the concept of genes and the principles underlying the process of gene expression in life forms.

Units	Topics	Number
		of
		Lectures
1	Information flow in biological systems:	
	•Central dogma, Properties of DNA: UV absorption,	
	Denaturation and	
	renaturation kinetics thermodynamics of melting of the	
	double helix, kinetics of unwinding of the double helix,	
	Interaction with small ions.	
	Genome Structure and Gene family:	
	Chromatin organization and remodelling, chromosome,	
	centromere, telomere.	
	•Gene families, clusters, Pseudogenes, super-families	
	•Organelle genomes. C-value paradox and genome size, Cot	
	curves,	
	repetitive and non-repetitive DNA sequences, Cot ½ and Rot	
	½ values, satellite DNA, DNA melting and buoyant density.	
	•Mobile genetic elements: Transposable elements in	
	bacteria, IS	
	elements composite transposons, replicative and non-	
	replicative	
	transposons, Mu transposition, Controlling elements in TnA and Tn 10	
	transposition.	
	•Transposable elements of Eukaryotes: Maize, Drosophila	
	and Yeast.	
	SINES and LINES, retrotransposons	8
2	Mechanism of Replication:	
	•Mechanism of prokaryotic DNA replication, models of	
	replications in	
	prokaryotes. Eukaryotic DNA polymerases and mechanism of	
	replication.	10

3

Gene

RNA).

Silencing:

•Co and post translational mechanisms

Telomere synthesis-Telomerases, Replication of viral DNA, model. **Inhibitors** of rolling circle replication. Homologous site-specific Recombination and recombination. •Models for homologous recombination-Holliday junction, NHEI, Proteins involved in recombination- RecA, RuvA, B, C, conversion Gene • DNA damage and Repair: DNA damage- alkylation, deamination, oxidation, UV radiation. Repair mechanismsphoto reactivation, excision repair, post replication repair, mismatch repair and SOS repair **Gene Expression in Prokaryotes and Eukaryotes** •Mechanism of Transcription: Mechanism of transcription and regulation function of bacterial RNA polymerases. Eukaryotic **RNA** polymerases-transcription factors. mechanism of transcription and regulation. •Post transcriptional modifications of mRNA: Caping, polyadenylation, mechanism of splicing, Group I, II and III, spliceosome assembly, splicing editing, Group IV splicing Processing of tRNA and rRNA. Inhibitors of transcription. •Translation mechanisms in prokaryotes and eukaryotes: detailed processes •Regulation of Gene expression in prokaryotes: Operon model-Inducible and repressible systems. Attenuation, positive and negative regulation with respect to tryptophan and arabinose operon. Role of cAMP and CRP in the expression of lac genes, catabolite repression with respect to lactose operon. •Regulation of gene expression in eukarvotes: transcriptional control, cis control elements, promoters, enhancers, transacting factors, homeobox in the control of developments in insects and vertebrates. DNA binding motifs of transcription factors, posttranscriptional control.

concept, transcriptional

transcriptional gene silencing, RNAi pathway (si RNA and mi

12

and

post

- 1. Genes XI, (2012), 11th edition Benjamin Lewin, Publisher Jones and Barlett Inc. **USA**
- 2. Molecular Biology of the Gene (2008). 6th Edition James D. Watson, Tania Baker, Stephen P. Bell, Alexander Gann, Michael Levine, Richard Lodwick. Pearson Education, Inc. and Dorling Kindersley Publishing, Inc. USA
- 3. Molecular Biology, (2011), 5th Edition. Weaver R., McGrew Hill Science. USA
- 4. Fundamentals of Molecular Biology, (2009), Pal J.K. and Saroj Ghaskadbi, Oxford University Press. India
- 5. Molecular Biology: genes to proteins. (2011), 4th edition. Burton E Tropp, Jones & Bartlett Learning, USA
- 6. Nucleic acids in Chemistry and Biology; (2022), 4th Edition, G. M. Blackburn, Martin Egil, Michael J Gait, Jonathan k Watts, RSC Publication, UK.

Course Code and title: PSBT-113A Genetics

Credits:02 **Total Lectures: 30**

- 1. To study of mendelian and non mendelian genetics.
- 2. To understand genetics of flowering, self-incompatibility, androgenesis, apomixis in angiosperms.
- 3. To understand the medical genetics and its clinical significance
- 4. To study population genetics, importance of genetic mapping, marker technology with special reference to recent trends in the field of genetics

Units	Topics	Number
		of Lectures
1	Overview of Mandelian genetics	Lectures
1	 Overview of Mendelian genetics. Concepts of exceptions to Mendel's laws. Advanced Genetics, Genetics of Flowering in Angiosperms, Genetics of Androgenesis, Genetics of apomixis, self-incompatibility, mutation studies. Genetics of Drosophila as a model organism. Hypomorphy, genetic mosaics, genetic epistasis in context 	8
	of developmental mechanisms.	
2	Population genetics and genetics of evolution. • Introduction to the elements of population genetics: genetic variation, genetic drift, neutral evolution; mutation selection, balancing selection, Fishers theorem, Hardy Weinberg equilibrium, factors affecting Hardy Weinberg equilibrium (selection, mutation, migrations and genetic drift) • In-breeding depression & mating systems; population bottlenecks, , Bayesian statistics; adaptive landscape, spatial variation & genetic fitness.	6
3	 Human genetics and methodologies Clinical genetics, diagnostic tools and techniques for human genetic disorder Genetic approaches to complex genetic diseases-hypertension, diabetes and Alzheimer's. Genetics of Cancer 	8
4	Genetic Mapping Genetic recombination and linkage • Genetic mapping and physical mapping • Molecular markers & marker based genetic linkage maps • Linkage Disequilibrium Genome-wide association study and haplotype mapping Applications of genetic maps	8

- 1. Hartl, D. L., & Jones, E. W. (1998). Genetics: Principles and Analysis. Sudbury, MA: Jones and Bartlett.
- 2. Pierce, B. A. (2005). Genetics: a Conceptual Approach. New York: W.H. Freeman.
- 3. Principles of Genetics 5th Edition by D. Peter Snustad (Author), Michael J. Simmons (Author)
- 4. Genetics Author B. D. Singh Edition 2, reprint Publisher Kalyani Publishers
- 5. Genetic Mapping and DNA Sequencing edited by Terry Speed, Michael Waterman

Course Code and title: PSBT-113B Immunology

Credits:02 **Total Lectures: 30**

- 1. To introduce different types of immunities and components of immune system
- 2. To understand interaction between antigens and antibodies, the basic principle behind the immunodiagnostic techniques.
- 3. To introduces different types of vaccines and development of vaccines

Units	Topics	Number
		of
		Lectures
1	Immunology:	6
	• Fundamental concepts and overview of the immune system	
	• Components of innate and acquired immunity;	
	phagocytosis; complement and inflammatory responses;	
	pathogen recognition receptors (PRR) and pathogen	
	associated molecular pattern (PAMP);	
	• innate immune response; mucosal immunity;	
	• antigens: immunogens, haptens;	
	Major Histocompatibility Complex: MHC genes,	
	•Organs of immune system, primary and secondary	
	lymphoid organs Immune Dysfunction and Its Consequences	
2	Immune responses generated by B and T lymphocytes	12
	• Immunoglobulins - basic structure, classes & subclasses of	
	immunoglobulins, Immunoglobulin super family.	
	antigenic determinants;	
	• multigene organization of immunoglobulin genes;	
	B-cell receptor;	
	B cell maturation, activation and differentiation;	
	• generation of antibody diversity;	
	• T-cell maturation, activation and differentiation and T-cell	
	receptors;	
	• functional T Cell subsets; cell-mediated immune responses,	
	• ADCC;	
	• cytokines: properties, receptors and therapeutic uses;	
	• antigen processing and presentation- endogenous antigens,	
	exogenous antigens	
3	• Terminologies for assessing antigen antibody interaction:	6
	Specificity, Affinity, Avidity, titer	

	• Antigen-antibody interactions Precipitation, agglutination	
	and complement mediated immune reactions	
	• Advanced immunological techniques: RIA, ELISA, Western	
	blotting, ELISPOT assay, immune fluorescence microscopy,	
	flow cytometry and immunoelectron microscopy; surface	
	plasmon resonance.	
	•Biosensor assays for assessing ligand –receptor	
	interaction; CMI techniques: lymphocyte proliferation assay,	
	mixed lymphocyte reaction	
4	Vaccinology:	6
	• History of vaccine development: Active and passive	
	immunization; live, killed, attenuated, subunit vaccines;	
	Vaccine technology: role and properties of adjuvants,	
	recombinant DNA and protein based vaccines, plant-based	
	vaccines, peptide vaccines, conjugate vaccines;	
	• T cell based vaccine. Phage display as a tool for vaccine and	
	immunotherapy development	

- 1. Kindt, T. J., Goldsby, R. A., Osborne, B. A., & Kuby, J. (2006). Kuby Immunology. New York: W.H. Freeman.
- 2. Brostoff, J., Seaddin, J. K., Male, D., &Roitt, I. M. (2002). Clinical Immunology.London: Gower Medical Pub.
- 3. Murphy, K., Travers, P., Walport, M., & Janeway, C. (2012). Janeway's Immunobiology. New York: Garland Science.
- 4. Paul, W. E. (2012). Fundamental Immunology. New York: Raven Press.
- 5. Goding, J. W. (1996). Monoclonal Antibodies: Principles and Practice: Production and Application of Monoclonal Antibodies in Cell Biology, Biochemistry, and Immunology. London: Academic Press.
- 6. Parham, P. (2005). The Immune System. New York: Garland Science.

Course Code and title: PSBT-114 Lab Course I: Practicals Based on Biological Chemistry, Cell Biology, Molecular Biology, Genetics and Immunology

Credits: 04 **Total Practicals: 30**

- 1. To study the process of enzyme extraction, purification and enzyme kinetics
- 2. To learn to isolate, analyze and quantify cell organelles and biomolecules
- 3. To learn the technique of various immunodiagnostic procedure based on antigen antibody interactions.
- 4. To solve logical and numerical problems based on concepts in population genetics and non-mendelian gene interaction.

Units	Topics	Number
		of
		Practicals
1	Isolation of nuclei and chromatin, Mononucleosome size	2
	determination by agarose gel electrophoresis	
2	Extraction and Analysis of Histones	2
3	Isolation of RNA and analysis by agarose gel	1
4	Isolation of genomic DNA and quantification by UV spectrophotometry	1
5	Isolation of mitochondria and lysosomes and assay of SDH and acid phosphatase activity respectively	1
6	Programmed cell death during limb development In Chick	1
7	Staining of animal cells (Histone by Fast green; DNA by Feulgen; RNA by Methyl green Pyronin)	1
8	Separation of mononuclear cells by Ficoll-Hypaque and their cryopreservation	1
9	Separation of leucocytes by dextran method	1
10	Double diffusion, Immuno-electrophoresis and Radial-Immuno diffusion, Rocket Immunoelectrophoresis	4
11	Widal test	1
12	Antibody titre by ELISA method/Western blotting	2
13	Extraction, purification and characterization of protein: Beta	
	galactosidase	
	 Extraction and assay of enzyme activity 	
	• Isolation, precipitation and Dialysis	
	• Enzyme Purification by using Column Chromatography- Ion	
	exchange/ Gel filtration	
	Characterization by Native and SDS PAGE.	_
	 Calculation of Km and Vmax of purified enzyme 	7

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14	Problems based on Population genetics, gene interactions	2
15	Isolation of secondary metabolites from a natural source. Methods	
	of extraction: Single step and Multi step Extractions; Hot and Cold	
	Extractions. Purification of extracts using separation techniques	
	(TLC, Column Chromatography etc.)	2
16	Visit to any Research Institute/laboratory and Report writing	1

- 1. Introduction to Practical Biochemistry, (2000), S. K. Sawhney, Randhir Singh Narosa,
- 2. Practical Enzymology, 2nd edition (2011), Hans Biss Wanger, Wiley-Blackwell, USA.
- 3. Biochemical Calculations, (1997), 2nd Edition, Segel Irvin H., Publisher: John Wiley and Sons, New York.
- 4. Enzymes: Biochemistry, Biotechnology & Clinical chemistry, (2001) Palmer Trevor, Publisher: Horwood Pub. Co., England.
- 5.An Introduction to Practical Biochemistry. (2001), 3rd Edition, David Plummer, Tata McGraw Hill Edu.Pvt.Ltd. India
- 6.Biochemical Methods.1st , (1995), S.Sadashivam, A.Manickam, New Age International Publishers, India

Course Code and title: PSBTELE-115A Environmental Biotechnology

Credits: 02 **Total Lectures: 30**

Course Outcomes:

1. To develop a basic understanding and awareness about the concepts of biotic and abiotic factors of the environment and the principles of biodiversity.

2. To generate awareness about sustainable development goals, Environmental Impact assessment, environmental laws and policies

Units	Topics	Number of Lectures
1	Energy and Environment	
	• Introduction to environmental Science Natural energy	2
	resources and their exploitation (Conventional)	
2	Pollution and Environment	
	• Introduction to environmental components, carbon foot	2
	prints, causes and consequences of climate change (global	2
	warming, Ozone hole, Sea level rise),	
3	Waste management -	
	• waste water analysis - BOD, COD theory in detail and	
	their experimental techniques.	
	• waste water technology - waste water treatment plant,	7
	Activated sludge process and its mathematics,	/
	• Solid waste management: Sources and types, Impact of	
	solid waste disposal, Recycle, Reuse and Recovery	
	solutions	
4	Bioremediation Removing Pollutants from	
	Environments-	
	 Use of biological agents in pollution control, 	
	• Types of Bioremediation (Advantages, limitations,	
	applications, Principle, natural and engineered any one	
	case study) and Factors affecting.	7
	• Xenobiotic degradation by microbes (enzymes involved	
	and any case study),	
	Biomining, Biomethanation, Bioleaching,	
	•Bio plastic technology, Bio plastic types,	
	Phytoremediation	
5	Environment monitoring Remote sensing:	
	• Principle, and objectives, Energy sources for remote	6
	sensing,	

	• Types of remote sensing, Applications- Agricultural,	
	Forestry Wildlife Ecology (any case study from the above	
	applications of remote sensing) and Environmental	
	Informatics	
	• Environmental Impact Assessment: Introduction,	
	Objectives, Classification, and Guidelines. Case Study.	
	• Environmental Audit: Introduction, Types, General	
	Methodology, International and Indian Eco-standards	
	ISO14000 series overview.	
6	Environmental Laws and Policies International:	
	• in the view of global concerns,	
	• objectives of laws/regulations,	
	• importance Stockholm conference,	
	Nairobi declaration,	6
	• Rio conference,	
	• India: Environmental Policy, Anti-Pollution Acts: The	
	water Act. 1974, The Air Act 1981, The Environment	
	Protection Act 1986- Their important objectives	

- 1. Alternative Energy: S. Vandana; APH Publishing Corporation
- 2. Groundwater Geochemistry: Fundamentals and Applications to Contamination, 1997, William J. Deutsch, Lewis Publishers
- 3. Agenda 21: Guidelines for Stakeholders Patwardhan & Gunale
- 4. Bioremediation (1994) Baker, K.H and Herson, D.S.McGraw Hill, Inc. New York
- 5. Biotreatment of Industrial & Hazardous Waste (1993) M.V.Levin and Gealt, M.A McGraw Hill. Inc
- 6. Ecology and environmental biology (2011) Saha T K Books & Allied (p) Ltd edition, Prentice Hall, Inc.
- 7. Environment Impact Assessment (1996) Larry W. Canter McGraw-Hill Book Company
- 8. Environmental biotechnology (2010) Rana Rastogi Publications
- 9.Soil and Water Conservation Engineering (1981) G. O. Schwab, Richard K. Frevert, Talcott W. Edminster, and Kenneth K. Barnes
- 10. Textbook of Remote sensing and GIS (2006) M. Anji Reddy 3rd
- 11. Waste Water Engineering: Treatment and Reuse (2002) Met Calf & Eddy INC, Tata mc raw Hill edition, Prentice-Hall

Course Code and title: PSBTELEP-115A Practicals in Environmental Biotechnology

Credits: 02 **Total Practicals: 15**

Course Outcomes:

- 1. To learn basic methods used for soil and water analysis,
- 2. To study genotoxic and cytotoxic effects of water pollution, Biochemical and chemical oxygen demand
- 3. To get introduced to GIS.

Units	Topics	Number of
		Practicals
1	Water Analysis-	
	Determination of biological oxygen demand and chemical	
	oxygen demand of sewage sample.	3
	Estimation of Total Solids	
2	Genotoxicity assay on polluted water- Onion root tip and	2
	pollen germination assay.	۷
3	Bioburden assay of wastewater	1
4	Anaerobic digestion of wastewater sample	1
5	Study of soil characteristics: Colour/texture/Water	1
	holding capacity/pH/Alkalinity/Organic content	1
6	Removal and estimation of pollutant from soil/water	1
	samples by biostimulation/ phytoremediation	1
7	Qualitative and quantitative estimation of biodegradation	1
	of pesticide/ insecticide/fungicide.	1
8	Acquisition of "Google Earth" images for the known and	
	unknown area for land use - land cover mapping	2
9	Review on EIA case study.	2
10	Visit to Waste Water Treatment Plant/ Waste recycling	1
	plant/ Water-Soil testing laboratory	1

- 1. Textbook of Remote sensing and GIS (2006) M. Anji Reddy 3rd
- 2. Waste Water Engineering: Treatment and Reuse (2002) Met Calf & Eddy INC, Tata mc raw Hill edition, Prentice-Hall

Course Code and title: PSBTELE-115B Food Biotechnology

Credits:02 **Total Lectures: 30**

Course Outcomes:

1. To learn basics and application of biotechnology in fermentation, nutraceuticals and, prebiotics and probiotics,

2. To get awareness regarding different laws in the food industry and QA and QC of food.

Units	Topics	Number of
		Lectures
1	 Microbial biotechnology Genetically modified microorganisms Fermentation Technology- Use of microbes in the production of alcohols (Beer, Wine), bread, Yogurt, Organic acids (Acetic acid, Lactic acid, Citric acid), Vitamins Pigments, Flavors, sweeteners Enzyme in Food Technology Production of food related enzymes- Amylases, Proteases, Lipases, Cellulases, Pectinases. Applications of these enzymes in food processing Applications of Biotechnology in food waste management and development of value added products 	9
2	Prebiotics and Probiotics • Food Sources- Prebiotics [Dietary fibre, Oligosaccharides (Galacto-oligosaccharides, Fructo-oligosaccharides), Resistant Starch, Sugar alcohols], • Traditional Fermented Foods as sources of Probiotics Role in Health and Disease, Mechanism of Action, Levels of Probiotics required for therapeutic efficacy	5
3	 Nutraceuticals Nutraceuticals Concept of Neutraceuticals and functional foods Major nutraceuticals and their health applications-Bioactive peptides, Curcumin, Conjugated Linoleic acid, Glucosamine, Carnitine, Creatine Safety and adverse effects associated with the consumption of functional foods and nutraceuticals 	6

	Recent trends in food formulation; antioxidant rich food products; concepts for formulation of foods for drought and disaster afflicted; defense services, sportsmen, space food	
4	Food Processing: • Definition and Difference between Food Processing and Food Preservation; Functions, Benefits and Drawbacks of Food Processing • Primary Processing Techniques – dicing, slicing, mincing, macerating, liquefaction, emulsification • Novel Food Processing – mushrooms, algae, leaf protein concentrates, protein from yeast, food analogues, edible insects	5
5	Role of QC and QA Quality: • Quality Control, Quality Assurance, Concepts of quality control and quality assurance functions in food industries • Food Laws Food Laws and Standards: National and International food laws overview	5

- 1. Anthony Pometto (2005). Food Biotechnology, 2nd Edition. CRC Press
- 2. Byong H Lee (2014). Fundamentals of Food Biotechnology, 2nd Edition, Wiley Blackwell
- 3. Goldberg, I 1994. Functional Foods: Designer Foods, Pharma foods, Nutraceuticals Chapman & Hall
- 4. Gibson, GR and William, CM. 2000. Functional foods Concept to Product. Woodhead publishing.
- 5. Aluko, R.E. (2012). Functional Foods and Nutraceuticals. Springer
- 6. Inteaz Alli. 2004. Food Quality Assurance: Principles and Practices. CRC Press, Boca Raton, FL,USA.
- 7. Ronald H. Schmidt and Gary E Rodrick. 2003. Food Safety Handbook. John Wiley & Sons, Inc., Hoboken. New Jersey, USA.

Course Code and title: PSBTELEP-115B Practical in Food Biotechnology

Credits: 02 **Total Lectures: 30**

Practicals:

1	Lab scale production and estimation of acetic acid	2
2	Testing of food adulteration (milk/milk products/any food sample)	1
3	Extraction and Detection of Aflatoxin in foods	2
4	Isolation and identification of starter organisms from fermented food	2
5	Lab scale production and estimation of quality of cheese	2
6	Isolation and identification of probiotics from fermented food	2
7	Isolation, extraction and characterization of curcumin by TLC	2
8.	Emulsions and Emulsifying Agents – Preparation of Mayonnaise & Vinaigrettes	2

Semester II

Course Code and title: PSBT-121 Genetic Engineering

Credits: **Total Lectures: 60**

- 1. To develop an approach towards applications of molecular biology techniques in developing recombinant molecules.
- 2. To understand the concept of genetically modified organisms.
- 3. To develop the basic conceptual underlying of advanced molecular biology techniques

Units	Topics	Number
	Topics	of
		Lectures
1	Introduction and tools for genetic engineering	
	 Impact of genetic engineering in modern society; 	
	• general requirements for performing a genetic engineering experiment;	
	• endo and exonucleases, RNAses, restriction endonucleases and	
	methylases; DNA ligase, <i>E.coli</i> DNA polymerase, Klenow	
	enzyme, T4 DNA polymerase, polynucleotide kinase, alkaline	
	phosphatase; cohesive and blunt end ligation;	
	• linkers; adaptors; homopolymeric tailing;	
	• labelling of DNA: nick translation, random priming, radioactive and non-radioactive probes	
	• hybridization techniques: northern, southern, south-western	
	and far-western and colony hybridization, fluorescence in situ	
	hybridization.	12
2	Different types of vectors	
	 Plasmids- pBR322. pBR 325, PUC19 and Bluescript vectors, 	
	 Bacteriophages M13 mp vectors, phagemids, 	
	 Lambda vectors; Insertion and Replacement vectors, 	
	• Cosmids,	
	 Artificial chromosome vectors (YACs; BACs), 	
	 Expression vectors: pMal, GST, pET-based vectors; 	
	 Mammalian expression and replicating vectors 	
	 Baculovirus and Pichia vectors system, 	
	 yeast vectors, shuttle vectors, Intein-based vectors 	12
3	Different types of PCR techniques,	12

	• Principles of DCD primer design.	
	Principles of PCR, primer design; fidelity of thermostable engages.	
	• fidelity of thermostable enzymes,	
	• DNA polymerases,	
	• types of PCR – multiplex, nested; reverse-transcription PCR,	
	real time PCR, touchdown PCR, hot start PCR, colony PCR,	
	asymmetric PCR, cloning of PCR products;	
	 PCR based site specific mutagenesis; 	
	PCR in molecular diagnostics for viral and bacterial detection;	
	• Sequencing methods: enzymatic DNA sequencing; chemical	
	sequencing of DNA; automated DNA sequencing, RNA	
	sequencing; chemical synthesis of oligonucleotides;	
	• Mutation detection: SSCP, DGGE, RFLP.	
4	Gene manipulation and protein-DNA interaction	
	• Insertion of foreign DNA into host cells, transformation,	
	electroporation, transfection; transduction- viral vectors,	
	• construction of libraries; isolation of mRNA and total RNA;	
	reverse transcriptase and cDNA synthesis; cDNA and genomic	
	libraries;	
	• construction of microarrays – genomic arrays, cDNA arrays and	
	oligo arrays;	
	• Study of protein-DNA interactions: electrophoretic mobility	
	shift assay;	
	DNase footprinting; methyl interference assay,	
	• chromatin immunoprecipitation.	12
5	Gene silencing and genome editing technologies	12
	• Gene silencing techniques;	
	• introduction to siRNA; siRNA technology; Micro RNA;	
	construction of siRNA vectors; principle and application of gene	
	silencing;	
	• gene knockouts,	
	• Genome editing by CRISPR-CAS with examples,	
	• Cre Lox P recombination system	
	• Genetic diseases-Detection and Diagnosis,	
	• Gene therapy – ex vivo, in vivo,	
	• DNA fingerprinting, Genetically engineered biotherapeutics	
	and	
	vaccines and their manufacturing	12

- 1. Principles of Gene Manipulation: An Introduction to Genetic Engineering (2001). Old, R. W., Primrose, S. B., &Twyman, R. M. Oxford: Blackwell Scientific Publications.
- 2. Green, M. R., &Sambrook, J. (2012). Molecular Cloning: a Laboratory Manual. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press.
- 3. Brown, T. A. (2006). Genome (3rd ed.). New York: Garland Science Pub.
- 4. Principles of gene manipulation and genomics. (2006) 7th Edition. Sandy Primrose and Richard Twyman, Blackwell Publishing.
- 5. Gene cloning and DNA analysis: An introduction. (2010) 6th Edition. T. A Brow. Willey-**Blackwell Publications**
- 6. From genes to genomes. Concepts and applications of DNA Technology. (2012) 3rd Edition. J. W. Dale, M.V. Schantz, N. Plant. Willey-Blackwell Publications

Course Code and title: PSBT-122 Bacteriology and Virology

Credits:04 **Total Lectures: 60**

- 1. To help students to understand the basic concepts of bacterial and viral classification,
- 2. To Understand structure, pathology and applications of bacteria in different fields

Units	Topics	Number
		of
		Lectures
1	New approaches in bacterial taxonomy	
	• (numerical taxonomy, ribotyping, rRNA sequencing, fatty acid	
	profile) ribosomal RNA analyses for tracing microbial evolution,	
	genetic basis of evolution, evolution of physiological diversity.	
	 Concept of 'unculturable' bacterial diversity. 	
	 Strategies for culture of 'unculturable' bacteria 	
	• The measurement of microbial diversity, Measures and indices of	
	diversity.	6
2	Ultrastructure of Bacteria :	
	 Cell wall (Gram positive, Gram negative and Archea), 	
	 Cell membrane (Gram positive, Gram negative and Archea), 	
	• Spore (endospore formation, germination, genetic basis and	
	structure), • Flagella (Assembly, Chemotaxis mechanism)	
	• Capsule, Fimbriae and Pilli,	
	• Cell inclusions	
	• Siderophores – Structure, Function and Significance	10
3	Extremophiles:	
	• Archea, adaptations in extremophiles (acidophiles, halophiles,	
	psychrophiles	
	 Applications in biotechnology 	4
4	Applied Bacteriology:	
	• Bacteriology and Public health: Mycobacteria, Enteric bacteria	
	(One example each, Pathogenicity, Virulence and methods of	
	identification), Quorum Sensing (Concept and significance in	
	Biofilm and pathogenicity of Bacteria)	
	• Bacteriology and Agriculture: Biofertlizers, Biopesticides, Mass	
	production of biofertilizers and quality control, Role of	
	Agrobacterium	
	• Pre and Probiotics	8

	Bacteriology and environment: Bioremediation (Petroleum and	
	Xenobiotic)	
	Microbial Fuel Cells	
	Bioluminescence	
	Bio surfactants	
5	Introduction to viruses:	
	General properties of viruses	
	Morphology and ultrastructure of Viruses,	
	Virus related structures – Viroid's and Prions	
	Classification of viruses: ICTV system, Baltimore system	4
6	Replication of viruses:	-
	Mechanism of virus adsorption and entry into host cell	
	Genome replication	
	Post transcriptional processing	
	Translation of viral proteins	
	Protein nucleic acid interactions and genome packaging	
	Assembly, exit and maturation of progeny virions	8
7	Bacteriophages:	
	Morphology, Genome organization and Life cycle of lambda	
	phage, M13	3
8	Cultivation of viruses:	
	In ovo: using embryonated chicken eggs	
	In vivo: using experimental animals	
	• Ex vivo / In vitro: using various cell cultures - primary and	
	secondary cell lines, suspension cell cultures and monolayer cell	
	culture	
	In plants and plant cell cultures	5
9	Viral Diagnosis:	
	Microscopy, Cultivation, Serological and Molecular methods,	
	Infectivity assays, immunodiagnostics Antivirals:	
	Physical and Chemical agents, Therapeutic agents, Vaccines	
	• Viral Interference and Interferons. Nature and source of	
	interferons, Classification of interferons.	7
10	Animal, Plant and Poultry viruses:	
	Diseases and Importance with examples	
	• Re-emerging and New emerging viral diseases with example	_
	(Influenza, H1N1,SARS,Nipah and Marburg), Current outbreaks	3
11	Concept of Bioterrorism	2

- 1. Ingraham J. L. and Ingraham C.A. (2004). Introduction to Microbiology. 3rd Edition. Thomson Brooks / Cole.
- 2. Madigan M.T., Martinko J.M. (2006). Brock's Biology of Microorganisms. 11th Edition. PearsonEducation Inc.
- 3. Prescott L.M., Harley J.P., AND Klein D.A. (2005). Microbiology, 6th Edition. MacGraw Hill Companies Inc.
- 4. Salle A.J. (1971) Fundamental Principles of Bacteriology. 7th Edition. Tata MacGraw Publishing Co.
- 5. Stanier R.Y., Adelberg E.A. and Ingraham J.L. (1987) General Microbiology, 5th Edition.Macmillan Press Ltd.
- 6. Tortora G.J., Funke B.R., Case C.L. (2006). Microbiology: An Introduction. 8th Edition. Pearson Education Inc.
- 7. Wilson K. and Walker J.M. (2005) Principles and Techniques of Biochemistry and Molecular
- 8. Flint Jane. S. (1999), Principles of Virology 3rd edition, ASM (American Society of Microbiology) Press Publisher, 2 volumes. USA.
- 9. Bernard.N. Fields, Lippincott and Williams Wilkins, USA Field's Virology 2 volumes, 5th edition, (2006),

Course Code and title: PSBT-122 Plant Biotechnology

Credits: 04 **Total Lectures: 60**

Course Outcomes:

1. To understand the principles of plant tissue culture, cryopreservation, gene transfer methods and GMO technology.

- 2. To study the use of lower organisms (Algae and fungi) from a biotechnological perspective.
- 3. To broaden their research perspective in plant biotechnology.

Units	Topics	Number
		of
		Lectures
1	• History of Plant biotechnology,	
	• Overview of basic concepts of Plant tissue culture -	
	Micropropagation, Somatic embryogenesis, Artificial seeds,	
	In vitro androgenesis, Somatic hybridization, Cybridization,	4
	• Production of bio active secondary metabolites by plant	
	tissue culture. '	
	 Suspension culture: initiation, growth and application 	
2	Algal biotechnology –	
	• qualitative (product improvement, strain improvement)	
	and quantitative (yield) improvement in economically	
	important algae like Spiruluna, Dunaliella, Botrycoccus,	
	Chlorella.	
	Fungal biotechnology –	
	• qualitative (product improvement, strain improvement)	8
	and quantitative (yield) improvement in economically	
	important fungi like mushrooms (Agaricus, Pleurotus,	
	Lentinus),	
	yeasts- Aspergillus, industrially important fungi.	
	• Seed Plant Biotechnology: Qualitative and quantitative	
	improvement in economically important seed plants	
3	Cryopreservation	
	• Concept, theory and various methods and techniques of	6
	cryopreservation of plant culture till its revive back	
	Applications and Disadvantages of cryopreservation	
4	Genetic transformation Methods:	14
	• Ti plasmid &Ri Plasmid vectors.	17

	 Mechanism of T-DNA transfer to plants, 	
	• Agro infection,	
	• Plant viral vectors.	
	• Physical Methods: electroporation, microinjection and	
	particle bombardment and selection of transformants and	
	regeneration of transgenic plants.	
	• Selectable markers, Reporter genes and Promoters used in	
	plant vectors and their role in genetic transformation.	
5	Genetic manipulation	
	• Introduction,	
	 Transgenic plants for biotic and abiotic stress, 	
	 Production of secondary metabolites 	
	• Concept of Synthetic Biology for production of bioactive	
	secondary metabolites	14
	• Increase in productivity by manipulation of photosynthesis	14
	and nitrogen fixation, molecular farming (improvement in	
	protein, lipids, carbohydrates),	
	• vaccines, antibodies, therapeutic proteins, Approaches to	
	marker-free transgenics	
	• Debate over GM crops	
6	Marker assisted plant breeding and QTL mapping	
	 Introduction Concept and types of markers 	
	• Gene vs marker QTL mapping and marker- assisted	
	selection (MAS) QTL mapping techniques	
	• Important properties of ideal markers for MAS Selection for	
	major genes linked to markers	
	• Potential of marker-assisted selection for Crop	14
	improvement	
	• Practical applications of MAS. MAS for major genes or	
	improvement of qualitative and quantitative traits	
	• Marker-assisted backcrossing : MABC procedure and	
	theoretical and practical considerations	
	 Marker-assisted gene pyramiding 	

- 1. Chawla HC (2004) Introduction to plant biotechnology (Science Publ)
- 2. Altman A, Hasegawa PM (Ed) (2012) Plant Biotechnology and agriculture. Prospects for the 21st century (Academic press).
- 4. Bhojwani SS. &Razdan MK (1996). Plant Tissue Culture: Theory & Practice(Elsevier).

- 5. Slater A, Scott NW, Fowler MR (2008) Plant Biotechnology: the Genetic Manipulation of plants (Oxford Press)
- 6. Biotechnology in Crop Improvement, H S Chawla. International Book Distributing Company 1998
- 7. Gene transfer to Plants 1995, Polykus I and Spongernberg, G. Ed. Springer Scam.
- 8. Molecular Approaches to Crop Improvement 1991. Dennis Liwelly Eds. PP 16
- 9. Plant Biotechnology 1994, Prakash and Perk, Oxford & IBH Publishers Co
- 10. Plant Biotechnology: An Introduction to Genetic Engineering by Adrian Slater, Nigel W. Scott, Mark R. Fowler. Oxford University Press, 2008.
- 11. Anderson, J.A., S. Chao, and S. Liu, 2007: Molecular breeding using a major QTL for Fusarium head blight resistance in wheat. Crop Sci. 4.
- 12. Heffner, E.L., M.E. Sorrells, and Jannink, J.-L. 2009. Genomic selection for crop improvement. Crop Sc. 49: 1-12.

Course Code and title: PSBTP-124 Lab Course II: Practicals Based on Genetic Engineering, Bacteriology, Virology, and Plant Biotechnology

Credits: 04 **Total Practicals: 30**

- 1. To perform and analyze recombinant DNA protocols
- 2. To get hands on training in plant tissue culture technique
- 3. To learn to isolate viruses in embryonated eggs, virus titration, bacterial isolation, identification and staining technique
- 4. To visit a tissue culture laboratory.

Units	Topics	Number
		of
		Practicals
1	Plasmid DNA isolation and DNA quantitation	1
2	Restriction mapping of plasmid DNA	1
3	Genetic Transfer by Conjugation	2
4	Polymerase Chain Reaction and analysis by agarose gel	1
	electrophoresis	
5	Preparation of competent cells and their transformation with	2
	standard plasmids,	
6	Vector and Insert Ligation	1
7	Southern hybridization	2
8	Isolation of the following types of bacteria from natural samples.	4
	Identification of the bacteria to at least the Genus level using the	
	Bergey's Manuals: (The identification key must be designed for	
	each isolated and identified bacterium. Students are expected to	
	isolate at least one Genus from each group.)	
	Mesophilic bacteria /Thermophiles / Anaerobes (any one	
	method)	
9	Propagation of viruses in animals/tissue culture /embryonated	2
	eggs.	
10	Qualitative and quantitative detection of bacteriophages	1
11	Animal virus titration by Hemagglutination test	1
12	Electron microscopic observations of ultrastrucutre of animal	1
	viruses (Pox, Influenza, Rabies and TMV	
13	Chlorella or Spirulina culture establishments and study of its	1
	growth using suitable parameters	1
14	Mushroom cultivation/ Yeast Cultivation and Physicochemical	2
	analysis	

MSc I Biotechnology

15	In vitro induction of somatic embryogenesis and preparation of	1
	artificial seeds	1
16	Micropropagation: initiations, multiplication and subculture	2
17	Initiation of suspension culture for the production of secondary	2
	metabolites	2
18	Hairy root induction and confirmation of transgenic	2
19	Visit to tissue culture laboratory and report writing	1

References:

1. Molecular Cloning: a Laboratory Manual. (2012). 4th edition. Green, M. R. and Sambrook, J. Cold Spring Harbor Laboratory Press. NY

Course Code and title: PSBTELE-125A Clinical Research, Data Management and **IPR**

Credits: 04 **Total Lectures: 60**

- 1. To understand the regulatory requirements and different phases for conducting clinical trials and required documentation
- 2. To gain the knowledge of designing database, data management.
- 3. To know basics of IPR, copyrights and patents

Units	Topics	Number of
		Lectures
	CLINICAL RESEARCH AND DATA MANAGEMENT	
1	Introduction to Clinical Research Drug Development	
	Process	1
	Overview of Drug Development Process including	
	clinical trials phases	
2	Protocol Designing:	
	Definition of protocol, its importance and purpose	
	Protocol format: Chapters (Headings) and broad	
	contents of protocol	
	Important scientific and administrative aspect included	_
	in protocol	5
	Protocol writing team and role of each member Original and the second sec	
	Clinical trial design: Types of study designs	
	• Sampling, sample size, randomization, Inclusion &	
	Exclusion criteria	
2	Phases of clinical trial & Types of trials Cond Clinical Properties (CCP) ICH FC	
3	Good Clinical Practice (GCP)-ICH E6:	
	• Ethical Principles and their origin	
	• Ethics in clinical research: As per ICMR & GCP	
	• Ethics committees: Roles & responsibility of IEC and IRB	
	• Ethics in relation to vulnerable groups & special	5
	situations	
	• Responsibilities of Sponsors, Investigators & Regulators	
	ICH: Purpose, regulations & guidelines	
	Informed consent and Informed consent form Facential Decuments	
4	Essential Documents Drug Dogulatory Affaire (Clinical Trial)	4
4	Drug Regulatory Affairs (Clinical Trial)	4

	Regulatory Authority in India (DCGI & CDSCO)	
	Schedule Y of Drugs & Cosmetics Act	
	• International Scenario of Regulatory Aspects: FDA, CFR,	
5	Clinical Safety &Pharmacovigilance:	
	 Definitions of AE, ADR, SAE, 	
	Recording & reporting: Objectives & Importance	9
	Pharmaco vigilance: International procedures	3
	Pharmaco vigilance in India	
6	Monitoring of Clinical Trials	
	 Monitoring and its role in clinical trials 	2
	• CRF and other source documents relevant to monitoring	
7	Concept of Database and Clinical Data Management •	
	Concept and designing of Database,	
	Data management & IT in clinical research	
	• CRF designing	40
	Query raising and query resolution	10
	• EDC System and 21 CFR Part 11 compliance	
	Practical for Protocol Design, CRF Design and source	
	documentation	
	INTELLECTUAL PROPERTY RIGHTS	
8	General Regime of Intellectual Property Rights:	
	Overview and Historical Perspectives;	
	• Intellectual Property as an Instrument of Development;	
	Need for Protecting Intellectual Property- Policy	6
	Consideration- National Perspectives and International	U
	demands;	
	• TRIPS (Trade Related Intellectual Property Rights)	
	Agreement and International Treaties related to IPR	
9	Patents: Criteria of Patentability; types of patent	
	applications: provisional and complete specifications.	
	• Procedure for Filing Patent Applications, Patent	
	Granting Procedure;	8
	• Revocation, Patent Infringement and Remedies;	•
	• Relevant Provisions of the Biological Diversity Act, 2002;	
	• Commercialization of patented innovations; licensing –	
	outright sale, licensing, royalty;	
10	Copyright and Neighboring Rights - Conceptual	
	Framework, Copyright works, Ownership, transfer and	12
	duration of Copyright, Renewal and Termination of	

	Copyright, Neighbouring Rights, Infringement of	
	copyrights and remedies; Examples and Case study;	
	• Protection of Plant Varieties and Plant Breeders' Rights	
	- Protection of Plant Varieties and Farmers' Rights,	
	Authority and Registry, Registration of Plant Varieties and	
	Essentially derived variety, Duration, Effect of	
	Registration and Benefit Sharing; Examples and Case	
	study;	
11	Patent Specification Drafting Exercise	4

- 1. Katzung, B.G. Basic and Clinical Pharmacology, (2010) Prentice hall International
- 2. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
- 3. E6 Good Clinical Practice. Code, Document Title, Previously coded. E6(R2) Good Clinical Practice(GCP). Finalised Integrated Addendum: November 2016.
- 4. New Drugs and Clinical Trials Rules 2019
- 5. Website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
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- 7. Wadehra, B.L. Law Relating To Intellectual Property, (2011), Fifth Edition, Universal Law Publishing Co.Pvt. Ltd.
- 8. TIFAC 2002 Some questions and answers on Patents and Copyrights
- 9. Das, H K ,Text book of Biotechnology, (2010), 4thedition, Wiley India Pvt. Ltd, New Delhi
- 10. Chawala, H.S., Introduction to Plant Biotechnology, 3rdedition, Science Publishers
- 11. Hirvani R, Patents in Plant Breeding: Guarding the Green Gold-, Biotech News, (2009), vol 4.
- 12. Ganguli Prabuddh, Intellectual Property Rights, (2001), Tata McGraw-Hill Publishing Company Ltd.
- 13. Narayanan P, Law of copyright and Industrial Designs, (2010), Eastern Law House, Delhi
- 14. Office of the Controller General Of Patents, Designs & Designs & Trade, (CGPDTM): Manual of Patents/Manual of Industrial Design/Draft Manual of Trademarks

Course Code and title: PSBTELE-125A Medical Biotechnology

Credits: 04 **Total Lectures: 60**

- 1. to understand the cellular and molecular pathogenesis of the various diseases;
- 2. To understand molecular and cytological causes for various genetic disorders,
- 3. To understand various current diagnostics methods and therapies

Units	Topics	Number
		of
		Lectures
1	Introduction to medical biotechnology	2
	History and recent developments	
2	Basis of diseases and disorders	15
	• Microbial diseases- Types of infections - primary, secondary,	
	nosocomial, iatrogenic, zoonotic etc. Mechanisms of Bacterial	
	and viral pathogenesis (bacterial toxins, capsules, enzymes,	
	intracellular parasitism, antigenic variations etc. leading to	
	establishment of infections. with any one example of each)	
	• Genetic diseases- chromosomal disorders, single gene (cystic	
	fibrosis, hemophilia, Sickle cell anemia) and polygenic	
	disorders (Type 1 diabetes, Alzheimer Disease, breast cancer),	
	mitochondrial disorders	
	Metabolic disorders-	
	• Nutritional disorder: Kwashiorkor, Marasmus , Obesity,	
	Diabetes, Inborn errors of metabolism- 1) Protein-PKU,	
	Alkaptonuria and Maple syrupuria and Gauchers 2)	
	Carbohydrates - glycogen storage disorders, Cori's disease and	
	Pomes disease 3)Lipids- Atherosclerosis 4) Nucleic acids- Gout,	
	Lesch-Nyhan syndrome	
3	Diagnostic tools	18
	Types- physical (overview)	
	Biochemical- Enzyme, protein based, antibody based, PCR	
	based, microarrays based, cytogenetic methods including	
	karyotyping, FISH, GISH), nano-based	
	Principles of lab diagnosis of infectious diseases	4.0
4	Therapies- introduction to various therapeutic agents	18
	Gene therapy	
	 Proteins and enzymes in therapy 	

	 Chemotherapeutics - antibiotics and chemotherapeutic agents, viral agents, and antiviral drugs, chemotherapy for cancer treatment Stem cell therapy, tissue engineering Bioartificial organs Nanotechnology in therapeutics 	
5	Preventive measures- importance, overview of vaccines,	4
6	Societal, ethical, economical issues	3

- 1. Medical Biotechnology. 2014. 1st edition. B.R. Glick, T.L. Delovitch, C. L. Patten. ASM Press
- 2. Molecular Diagnostics. For the clinical Laboratorian. 2nd Edition W. B Coleman, G. S. Tsongalis. Human Press
- 3. Molecular Diagnostics. 2005. 1st edition. G. P. Patrinos, W. Ansorge. Elsevier Pulblications.
- 4. Human Molecular genetics. (2019). 5th edition. T. Strachan, A. Read. Garland Science.
- 5. Human Molecular genetics McConkey