



Savitribai Phule Pune University

(Formerly University of Pune)

Two Year Degree Program in Biotechnology

(Faculty of Science & Technology)

Revised Syllabi for

M.Sc. (Biotechnology) Part-I

(For Colleges Affiliated to Savitribai Phule Pune University)

Choice Based Credit System Syllabus

To be implemented from Academic Year 2019-2020

Title of the course: M.Sc. (Biotechnology)

Preamble:

Biotechnology has grown, extensively in last couple of decades. This advanced 'interdisciplinary' life science branch encompasses areas viz. molecular biology, genetics, biochemistry, microbiology, immunology, virology, plant and animal tissue culture, chemistry and engineering. It is a fast emerging "cutting edge" science with distinctive advantages as it finds applications in practically all aspects of life. The subject offers exciting opportunities in various fields from basic research to industry oriented career. Global and local focus has slowly shifted to using knowledge of life Science for innovative technology development that is being used for betterment of human life. Many fundamental research fields from cell biology to molecular biology, from biochemistry to biophysics, from genetic engineering to stem cell research, from bioinformatics to genomics-proteomics, from environmental biology and to biodiversity, from microbiology to bioprocess engineering, from bioremediation to *In silico* drug discovery etc. comes under the umbrella of Biotechnology.

The proposed choice based credit curriculum and grading system will cater to the existing interdisciplinary nature of biotechnology can also offer many courses to the other branches of life science. The generative power of biological data is effectively harnessed by biotechnology like no other field. Economic and social renaissance is staged on biotechnology especially, since it's biomedical and cutting edge technological applications are tremendously powerful in shaping this century and exciting biofuture. Keeping in view the expanse and applications of Biotechnology in every field, there is going to be a perpetual demand for resource personnel with Biotechnology specialization. The post graduate program is aimed to cater to this ever increasing demand and to groom the students to excel in their future career. Education and research sectors require such interdisciplinary trained workforce to develop future generations of science leaders.

Introduction:

Master's in Biotechnology course syllabus is revised to cater to the needs of credit based semester and grading system. The changing scenario of higher education in India and abroad is taken into consideration while restructuring this syllabus and more oriented towards current need of modern research and industrial sectors. The syllabus encompasses the fundamental academics at one end and latest technologies in life science at the other. Theory courses will help students develop their knowledge sets on various topics of biotechnology, to which, they are introduced at the undergraduate

level. Extensive practical courses are designed to supplement the theory courses with hands on experimentation in wet-lab and on fields. Empowerment of students to face research and industrial outlets is at the centre of this syllabus. Students having to select their own courses will develop the depth in specialization and also make them ready to face the upcoming scientific advances in the world without any further training. M.Sc. syllabus has been prepared keeping in vision the undergraduate curriculum. At the undergraduate level, students were introduced to many fundamental topics in life sciences such as molecular biology, developmental biology, fermentation technology, biodiversity, bioinformatics and tissue culture etc. At the post graduate level they will be also be acquainted with the thrust/new areas of biotechnology like bioinformatics, clinical research, data base management, IPR, Food Technology etc. to give the students the advantage of not only learning these subjects but also give them the edge over others in their employability. A research project/ industrial training modules are incorporated to provide a buffer zone for budding biotechnologists eager to enter the life science sector.

Objectives to be achieved:

- To help the students to build interdisciplinary approach
- To empower students to excel in various research fields of Life Sciences
- To inculcate sense of scientific responsibilities for social and environment awareness.
- To acquaint the students with thrust areas of biotechnology
- To adapt the internationally acknowledged Choice Based Credit System (CBCS) that offers opportunities to learn core subjects and to explore additional avenues of learning beyond the core subjects for complete development of an individual.

Course Structure:**Semester I**

Course code	Course Title	Credits
Core Compulsory Theory Papers (CCTP)		
MBT- 101	Advanced Biological Chemistry	4
MBT- 102	Cell & Molecular Biology	4
MBT- 103	Genetics & Immunology	4
Core Compulsory Practical Paper: CCP-1		
MBT- 104	Laboratory Course I - Advanced Biological Chemistry, Cell & Molecular Biology, Immunology	4
Choice Based Optional Papers: CBOP (any One)		
MBT -105	Environmental Biotechnology	4 (2T + 2P)
MBT -106	Food Biotechnology	4 (T)
Total		20 Credits

Semester II

CourseCode	Course Title	Credits
Core Compulsory Theory Papers (CCTP)		
MBT- 201	Genetic Engineering	4 Credits
MBT- 202	Bacteriology and Virology	4 Credits
MBT- 203	Plant Biotechnology	4 Credits
Core Compulsory Practical Paper : CCP-1		
MBT- 204	Laboratory Course II - Genetic Engineering, Bacteriology and Virology, Plant Biotechnology	4 Credits
Choice Based Optional Papers: CBOP (any One)		
MBT -205	Clinical Research, Data Base management, & IPR	4 Credits
MBT -206	Medical Biotechnology	4 Credits
Total		20 Credits

Semester III

Course code	Course Title	Credits
Core Compulsory Theory Papers (CCTP)		
MBT- 301	Animal & Stem Cell technology	4 Credits
MBT- 302	Bioprocess engineering	4 Credits
MBT- 303	Bioinformatics & Biostatistics	4 Credits
Core Compulsory Practical Course : CCP-1		
MBT - 304	Laboratory Course IV- Animal Biotechnology, Bioprocess engineering & Bioinformatics & Biostatistics	4 Credits
Choice Based Optional Papers: CBOP (any One)		
MBT - 305	Nano Biotechnology	4Credits (2T + 2P)
MBT - 306	Agricultural Biotechnology	4 Credits (2T + 2P)
Total		20 Credits

Semester IV

Course code	Course Title	Credits
Core Compulsory Theory Papers (CCTP)		
MBT- 401	Genomics and Proteomics	4 Credits
MBT- 402	Advanced Bio analytical Techniques	4 Credits
Core Compulsory Practical Paper : CCP-1		
MBT- 403	Research Project	4 Credits
Choice Based Optional Papers: CBOP (any Two)		
MBT - 404	Bio entrepreneurship & Start up Designing	4Credits
MBT - 405	Pharmaceutical Biotechnology & Drug Designing	4 Credits
MBT - 406	Research Methodology & Scientific Communication	4 Credits
MBT - 407	Quality Control, Bio safety & Bioethics	4 Credits
Total		20 Credits

Equivalence of previous syllabus along with proposed syllabus

Paper Title of Previous Syllabus	Equivalent Paper Title of New Syllabus
BT 101 Advanced Biological Chemistry	MBT 101 Advanced Biological Chemistry
BT 102 Molecular Biology	MBT – 102 Cell & Molecular Biology
BT 103 Environmental Biotechnology	MBT- 105 Environmental Biotechnology (CBOP)
BT 104 Cell Biology	MBT -102 Cell & Molecular Biology
BT 105 Exercises in Advanced Biological Chemistry	MBT – 104 Laboratory Course I - Advanced Biological Chemistry, Cell & Molecular Biology
BT 106 Exercises in Molecular and Cell Biology	MBT – 104 Laboratory Course I - Advanced Biological Chemistry, Cell & Molecular Biology
BT 107 Exercises in Environmental Biotechnology	MBT – 105 Environmental Biotechnology (CBOP)
BT 201 Genetic Engineering	MBT – 201 Genetic Engineering
BT 202 Immunology	MBT – 103 Genetics & Immunology
BT 203 Principles of Bacteriology and Virology	MBT – 202 Bacteriology and Virology
BT 204 Plant Biotechnology	MBT – 203 Plant Biotechnology
BT 205 Exercises in Genetic Engineering	MBT – 204 Laboratory Course II - Genetic Engineering, animal & Plant Biotechnology
BT 206 Exercises in Immunology	MBT – 104 Laboratory Course I - Advanced Biological Chemistry, Cell & Molecular Biology
BT 207 Exercises in Plant Biotechnology	MBT – 204 Laboratory Course II - Genetic Engineering, animal & Plant Biotechnology
BT 208 Exercises in Bacteriology and Virology	MBT 204 Laboratory Course II - Genetic Engineering, animal & Plant Biotechnology

Semester I**Course Code: MBT-101: Advanced Biological Chemistry:4 Credits****60 lectures**

Units	Topics	No. of Lectures
I	Protein Chemistry: <ul style="list-style-type: none"> • Structure of Proteins: Primary, Secondary, Tertiary, quaternary. Study of protein motifs and protein families. • Protein folding mechanisms and Pathways. Factors affecting stability- Molten globule, energy funnel, chaperons. • Protein misfolding and diseases • Protein –protein interaction and protein –DNA interaction • Structure –function relationship • Protein Engineering and its applications • Peptides and Therapeutic Proteins 	15
II	Enzymes: <ul style="list-style-type: none"> • Enzyme – Concept of active site, binding sites, Stereospecificity of enzyme and ES complex formation • Enzyme Activity, Various factors influencing enzyme activity and Enzyme inhibition • Mechanism of enzyme action and Enzyme regulation. Multienzyme complexes • Enzyme kinetics, Rate of reactions, steady state enzyme kinetics, Michaelis-Menten Equation - form and derivation. Significance of V_{max} and K_m, K_{cat}. Bisubstrate reactions. Graphical procedures in enzymology. Lineweaver Burke's Plot, EdieeHofstee plot • Clinical and Industrial Applications of enzymes Enzymes :Diagnostics and therapeutic enzymes used in a Biosensors (glucose oxidase, Cholesterol Oxidase), • .Enzyme Engineering and 	15
III	Metabolomics: <ul style="list-style-type: none"> • Overview of metabolism, Integration of Metabolism • The Metabolome – Metabolic flux, Metabolic flux analysis • Metabolic engineering – 2 eg. Polyketides Synthesis, Xenobiotics 	15
IV	Phytochemistry: <ul style="list-style-type: none"> • Introduction to secondary Metabolism, primary metabolite as precursors of secondary Metabolite • Pathways for secondary Metabolite <ol style="list-style-type: none"> 1. Mevalonate pathways 2. Shikimate Pathway 3. Isoprene Unit Pathways (IPP) 	15

	<ul style="list-style-type: none"> • Study of secondary Metabolite <ol style="list-style-type: none"> 1. Alkaloids 2. Phenolics 3. Terpenoids • Extraction methods & Qualitative & Quantitative Analysis 	
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Reference Books:

1. Proteins: Biotechnology and Biochemistry, 1st edition (2001), Gary Walsch, Wiley, USA
2. Phytochemical Method, 3rd edition (1998), A.J. Harborne, Springer, UK.
3. Pharmacognosy, 14th edition, (2008), Dr. C. K. Kokate, A. P. Purohit, S. B. Gokhale, NiraliPrakashan, India.
4. Trease and Evans' Pharmacognosy, 16th edition (2009), William Charles Evans, Saunders Ltd. USA.
5. Introduction to Practical Biochemistry, (2000), S. K. Sawhney, Randhir SinghNarosa, 2000. Practical Enzymology, 2nd edition (2011), HansBissWanger, Wiley-Blackwell, USA.
6. Biochemical Calculations, 2nd Ed., (1997) Segel Irvin H., Publisher: John Wiley and Sons, New York.
7. Enzymes: Biochemistry, Biotechnology & Clinical chemistry, (2001) Palmer Trevor, Publisher: Horwood Pub. Co., England.
8. Metabolic Engineering: Principles and Methodologies. (1998). Gregory N Stephanopoulos, Aristos A Aristidou, Jens Nielsen. Publisher: Academic Press, San Diego, US
9. Outlines of Biochemistry: 5th Edition, Erice Conn & Paul Stumpf ; John Wiley and Sons, USA
10. Fundamentals of Biochemistry. 3rd Edition (2008), Donald Voet& Judith Voet , John Wiley and Sons, Inc. USA
11. Lehninger, Principles of Biochemistry. 5th Edition (2008), David Nelson& Michael Cox, W.H. Freeman and company, NY.
12. Outlines of Biochemistry: 5th Edition, (2009), Erice Conn & Paul Stumpf ; John Wiley and Sons, USA
13. Biochemistry: 7th Edition, (2012), Jeremy Berg, LubertStryer, W.H.Freeman and company, NY
14. An Introduction to Practical Biochemistry.3rd Edition, (2001), David Plummer, Tata McGraw Hill Edu.Pvt.Ltd. India
15. Biochemical Methods.1st , (1995), S.Sadashivam, A.Manickam, New Age International Publishers, India

4 Credits

Semester I

60

Course Code: MBt-102- Cell & Molecular Biology:

lectures

Unit	Topics	No. of lectures
I	Cell structure and transport <ul style="list-style-type: none"> 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 	8
II	Cell communication <ul style="list-style-type: none"> Organelles and membrane trafficking Cell signalling: communication between cells and environment Extracellular matrix and cell junctions- relevance to tissue structure and function Signalling at cell surface, signalling molecules, hormones and receptors Signalling pathways that control gene activity, signal transduction and second messengers 	12
III	Cell Cycle and Cell Death Pathway <ul style="list-style-type: none"> Cell differentiation, , cell transformation in plants and animals Cell Cycle and its regulation: An over view of mechanics of Cell Division Assembly and disassembly of cytoskeletal elements, role in cell division Regulation of cell cycle events- Cyclins, Cyclin dependent kinases, inhibitors. Cell death Role of hormones and growth factors Programmed cell death Cell transformation and etiology of cancer 	10
IV	Information flow in biological systems: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Chromatin organization and remodeling, 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 $\frac{1}{2}$ and Rot $\frac{1}{2}$ values, satellite DNA, DNA melting and buoyant density. 	8

	<ul style="list-style-type: none"> • 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 	
V	<p>Mechanism of Replication:</p> <ul style="list-style-type: none"> • Mechanism of prokaryotic DNA replication, models of replications in prokaryotes. Eukaryotic DNA polymerases and mechanism of replication. Telomere synthesis-telomerases. Replication of viral DNA, rolling circle model. Inhibitors of replication. • Recombination Homologous and site-specific recombination, • Models for homologous recombination-Holliday junction, NHEJ, Proteins involved in recombination- RecA, RuvA, B, C, Gene conversion • DNA damage and Repair: DNA damage- alkylation, deamination, oxidation, UV radiation. Repair mechanisms- photoreactivation, excision repair, post replication repair, mismatch repair and SOS repair 	10
VI	<p>Gene Expression in Prokaryotes and Eukaryotes</p> <ul style="list-style-type: none"> • 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 : Capping, poly adenylation, mechanism of splicing, Group I, II and III, spliceosome assembly, splicing editing, Group IV splicing Processing of tRNA and rRNA. Inhibitors of transcription. • 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 eukaryotes: 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. • Gene Silencing: concept, transcriptional and post transcriptional gene silencing, RNAi pathway (si RNA and mi RNA). • Co- and post-translational modifications of proteins: Control of translation in eukaryotes (Antisense RNA, Heme and interferon). 	12

Reference Books

1. Molecular Cell Biology. 7th Edition, (2012) 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, 5th Edition (2007) Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, Peter Walter. Garland Science, USA
3. Cell Biology, 6th edition, (2010) Gerald Karp. John Wiley & Sons., USA
4. The Cell: A Molecular Approach, 6th edition (2013), Geoffrey M. Cooper, Robert E. Hausman, Sinauer Associates, Inc. USA
5. Genes XI, 11th edition (2012), Benjamin Lewin, Publisher - Jones and Barlett Inc. USA
6. Molecular Biology of the Gene, 6th Edition (2008), James D. Watson, Tania Baker, Stephen P. Bell, Alexander Gann, Michael Levine, Richard Lodwick. Pearson Education, Inc. and Dorling Kindersley Publishing, Inc. USA
7. Molecular Biology, 5th Edition (2011), Weaver R., McGraw Hill Science. USA
8. Fundamentals of Molecular Biology, (2009), Pal J.K. and SarojGhaskadbi, Oxford University Press. India 5. Molecular Biology: genes to proteins, 4th edition (2011), Burton E Tropp, Jones & Bartlett Learning, USA

Semester I**Course Code: MBT-103 Genetics and Immunology: 4 Credits****Total Lectures=60**

Unit	Topics	No. of lectures
I	<ul style="list-style-type: none"> • Overview of Mendelian genetics, Laws of segregation in plant crosses, inbreeding, selfing, heterosis, maintenance of genetic purity. • Drosophila genetics as a model of higher eukaryotes Monohybrid & dihybrid crosses, back-crosses, test-crosses, analyses of autosomal and sex linkages, screening of mutations based on phenotypes and mapping the same, hypomorphy, genetic mosaics, genetic epistasis in context of developmental mechanism. • Arabidopsis as model organism for genetic studies 	08
II	<p>Population genetics and genetics of evolution</p> <ul style="list-style-type: none"> • 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. 	08
III	<p>Human genetics and methodologies</p> <ul style="list-style-type: none"> • Clinical genetics, diagnostic tools and techniques for human genetic disorder Genetic approaches to complex genetic diseases- hypertension, diabetes and Alzheimer's 	08

IV	Genetic Mapping <ul style="list-style-type: none"> • 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 	06
V	Immunology: 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, MHC and immune responsiveness and disease susceptibility, Organs of immune system, primary and secondary lymphoid organs.	06
VI	Immune responses generated by B and T lymphocytes Immunoglobulins - basic structure, classes & subclasses of immunoglobulins, antigenic determinants; multigene organization of immunoglobulin genes; B-cell receptor; Immunoglobulin super family; principles of cell signaling; basis of self & non-self discrimination; kinetics of immune response, memory; 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.	12
VII.	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: lympho proliferation assay, mixed lymphocyte reaction.	06

VIII	Vaccinology <ul style="list-style-type: none"> • 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, chimeric, generation of monoclonal antibodies, hybrid monoclonal antibodies; and generation of immunoglobulin gene libraries. 	6
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Reference Books:

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. Tamarin, R. H., & Leavitt, R. W. (1991). Principles of Genetics. Dubuque, IA: Wm. C. Brown.
4. Smith, J. M. (1998). Evolutionary Genetics. Oxford: Oxford University Press
5. Kindt, T. J., Goldsby, R. A., Osborne, B. A., & Kuby, J. (2006). Kuby Immunology. New York: W.H. Freeman.
6. Brostoff, J., Seaddin, J. K., Male, D., & Roitt, I. M. (2002). Clinical Immunology. London: Gower Medical Pub.
7. Murphy, K., Travers, P., Walport, M., & Janeway, C. (2012). Janeway's Immunobiology. New York: Garland Science.
8. Paul, W. E. (2012). Fundamental Immunology. New York: Raven Press.
9. Goding, J. W. (1996). Monoclonal Antibodies: Principles and Practice: Production and Application of Monoclonal Antibodies in Cell Biology, Biochemistry, and Immunology. London: Academic Press.
10. Parham, P. (2005). The Immune System. New York: Garland Science.
11. Principles of Genetics 5th Edition by D. Peter Snustad (Author), Michael J. Simmons (Author)
12. Genetics Author B. D. Singh Edition 2, reprint Publisher Kalyani Publishers
13. Genetic Mapping and DNA Sequencing edited by Terry Speed, Michael Waterman

Semester I

Course Code: MBT 104 Laboratory Course I

(Advanced Biological Chemistry, Genetics and Immunology, Cell and Molecular Biology)

S.No.	Practical	Number of Practicals
1	Extraction, purification and characterization of protein : Beta galactosidase <ul style="list-style-type: none"> • Extraction and assay of enzyme activity • Isolation, precipitation and Dialysis • Enzyme Purification by using Column Chromatography- Ion exchange/ Gel filtration • Characterization by Native / SDS PAGE 	5
2	Study of Enzyme Kinetics of beta Galactosidase: <ul style="list-style-type: none"> • Effect of substrate concentrations on the rate of enzymatic reaction using Line Weaver Burk double reciprocal plot. • Determination of Km, Vmax and Kcat. 	3
3	Extraction and Qualitative/Quantitative estimation of phytoconstituents	1
4	Double diffusion, Immuno-electrophoresis and RadialImmuno diffusion	2
5	Complement fixation test.	1
6	Antibody titre by ELISA method	1
7	SDS-PAGE, Immunoblotting, Dot blot assays	1
8	Separation of mononuclear cells by Ficoll-Hypaque and their cryopreservation	1
9	Separation of leucocytes by dextran method.	1
10	Isolation of nuclei and chromatin Mononucleosome size determination by agarose gel electrophoresis	2
11	Extraction and Analysis of Histones	2
12	Isolation of RNA and analysis by agarose gel	1
13	Demonstration of PCR/RT-PCR using suitable genes	2
14	Restriction digestion of DNA using suitable RE and resolution on agarose gel.	1
15	Isolation of mitochondria and lysosomes and assay of SDH and acid phosphatase activity respectively	1
16	Programmed cell death during limb development In Chick	1
17	Staining of animal cells (Histone by Fast green; DNA by Fuelgen; RNA by Methyl green Pyronin).	1

18	Karyotyping and Ideogram construction in onion roots using Colchicine treatment	2
19	Visit to animal house, or any National Research Institute and Industry Report writing.	

Semester I

Course Code: MBT-105 Environmental Biotechnology

4 credits(2 T + 2P Credit Course)

Total Lectures=30

Unit	Topics	No. of lectures
I	Energy and Environment <ul style="list-style-type: none"> • Introduction to environmental Science • Natural energy resources and their exploitation (Conventional) 	2
II	Pollution and Environment <ul style="list-style-type: none"> • Introduction to environmental components, future scenarios of the global environment • Impact on environment (biotic & abiotic), transport and diffusion, monitoring, quality standards, carbon foot prints • causes and consequences of climate change (global warming, Ozone hole, Sea level rise), 	1 2 2
III	Waste management <ul style="list-style-type: none"> • Waste water technology, Activated sludge process, Removal of organic and inorganic pollutants • Solid waste management: Sources and types, Impact of solid waste disposal, Recycle, Reuse and Recovery solutions 	3 3
IV	Bioremediation Removing Pollutants from Environments <ul style="list-style-type: none"> • Introduction to use of biological agents in pollution control, Advantages, limitations and applications Principle, types of Bioremediation and Factors affecting: Natural, Engineered, <i>Ex-situ</i> and <i>in-situ</i> • Xenobiotic degradation, : Biomining, Biomethanation, Bioleaching, Bio plastic technology • Biological Fertilizer and pesticides. • Principles and methods in: Bioaugmentation, Biostimulation, Phytoremediation 	6

V	Environment monitoring	2
	<ul style="list-style-type: none"> • Remote sensing and GIS : Principal, and objectives, Energy sources for remote sensing, Types of remote sensing, Applications- Agricultural, Forestry, Water Resource Urban Planning, Wildlife Ecology, Environmental Informatics 	2
	<ul style="list-style-type: none"> • Environmental Impact Assessment: Introduction, Objectives, Classification, Guidelines. Case Study. • Environmental Audit: Introduction, Types, General Methodology, International and Indian Eco-standards ISO14000 series overview. 	2
IV	Environmental Laws and Policies	6
	<ul style="list-style-type: none"> • International: in the view of global concerns, objectives of laws/regulations, importance Stockholm conference, Nairobi declaration, Rio conference, • India: Environmental Policy , Anti Pollution Acts: The water Act. 1974, The Air Act 1981, The Environment Protection Act 1986- Their important objectives 	

Reference Books:

1. Alternative Energy: S. Vandana; APH Publishing Corporation
2. Bio-Energy Resources: Chaturvedi; Concept Pub.
3. Renewable Energy – Environment and Development: M. Dayal; KonarkPub.Pvt. Ltd.
4. Water Sheds, Cambridge University Press, 2004. Wiley & Sons Limited, 2004.
5. William J. Deutsch, Groundwater Geochemistry: Fundamentals and Applications to Contamination, Lewis Publishers, 1997.
6. Advanced Renewable Energy Sources (2012) GopalNathTiwari and R K Mishra, RSC Publishing
7. Agenda 21: Guidelines for Stakeholders Patwardhan&Gunale
8. An Introduction To Geographic Information Technology (2009) Suchandra Choudhury I K International Pvt Ltd.
9. Bioremediation (1994) Baker, K.H and Herson, D.S.McGraw Hill, Inc. New York
10. Biotreatment of Industrial & Hazardous Waste (1993) M.V.Levin and Gealt, M.A McGraw Hill. Inc
11. Concepts and Techniques of Geographic Information Systems (2009) C.P.Lo.Albert and K.W.Yeung 2nd
12. Ecology and environmental biology (2011) Saha T K Books & Allied (p) Ltd edition, Prentice Hall, Inc.
13. Environment Impact Assessment (1996) Larry W. Canter McGraw-Hill Book Company
14. Environmental Audit (2002) Mhaskar A.K. Enviro Media Publications
15. Environmental Biology (2000) Varma&Agarwal S. Chand Limited
16. Environmental biotechnology(2010) RanaRastogi Publications
17. Environmental Protection and Laws (1995) Jadhav and BhosaleV.M.Himalaya publishing House.

18. Environmental risks and hazards (1994) Susan Cutter Prentice Hall, Inc.
19. Environmental Science (2011) Santra S.C. New Central Book Agency
20. Remote sensing of the environment (2000) John R. Jensen Dorling Kindersley India Pvt. Ltd
21. Soil and Water Conservation Engineering (1981) G. O. Schwab, Richard K. Frevert, Talcott W. Edminster, and Kenneth K. Barnes
22. Textbook of Remote sensing and GIS (2006) M. Anji Reddy 3rd
23. Waste Water Engineering: Treatment and Reuse (2002) Met Calf & Eddy INC, Tata mc Graw Hill edition, Prentice-Hall
24. <http://envfor.nic.in/index.php>
25. <http://www.earthsummit2012.org/>

Semester I**Course code: MBT-105, Practical Course in Environmental Biotechnology****2 Credit Course****Total Practical =15**

Sr.No.	Topic	No. of practical
1	Removal and estimation of pollutant from soil/water samples by biostimulation/ phytoremediation	2
2	Genotoxicity assay on polluted water- Onion root tip and pollen germination assay.	2
3	Qualitative and quantitative estimation of biodegradation of pesticide/ insecticide/fungicide.	2
4	Estimation of Total suspended solids of waste water	1
5	Determination of dissolved oxygen concentration of water sample	1
6	Determination of chemical oxygen demand (COD) of sewage sample.	1
7	Determination of biological oxygen demand of sewage sample	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

Semester I
CourseCode: MBt- 106 Food Biotechnology
Elective 4 Credits Course

Total Lectures=60

Unit	Topic	No. of lectures
I	Microbes in Food Spoilage & Control <ul style="list-style-type: none"> • Types of micro-organism normally associated with food-mold, yeast, and bacteria, Microbial growth pattern, physical and chemical factors, influencing destruction of micro-organisms. • Micro-organisms in natural food products and their control. Biochemical changes caused by micro-organisms, deterioration and spoilage of various types of food products. • Food poisoning and microbial toxins, standards for different foods. Food borneintoxicants and mycotoxins. 	8
II	Microbial biotechnology <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 	5 5
III	Nanobiotechnology <ul style="list-style-type: none"> • Use of nanoparticles for delivery of bioactive constituents, nanoencapsulation, nanopackaging, nanosensors for detection of pesticides & pathogens • Applications of Nutrigenomics in the food industry • Ethical Concerns, Safety and Regulatory Issues of biotechnological products 	7
IV.	Prebioticsand Probiotics <ul style="list-style-type: none"> • Food Sources- Prebiotics [Dietary fibre, Oligosaccharides (Galacto-oligosaccharides, Fructo-oligosaccharides), Resistant Starch, Sugar alcohols], • Traditional Fermented Foods as sources of Probiotics 	10
Savitribai Phule Pune University		21

	<ul style="list-style-type: none"> • Strains of microorganisms used as probiotics Role in Health and Disease, Mechanism of Action, Levels of Probiotics required for therapeutic efficacy 	
V	Nutraceuticals <ul style="list-style-type: none"> • Concept of Nutraceuticals 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 • Recent trends in food formulation; antioxidant rich food products; concepts for formulation of foods for drought and disaster afflicted; defense services, sportsmen, space food 	9
VI	<ul style="list-style-type: none"> • Role of QC and QA Quality: Quality Control, Quality Assurance, Concepts of quality control and quality assurance functions in food industries. • Quality Improvement Total Quality management: Quality evolution, quality gurus, defining TQM, principals of TQM, stages in implementation, TQM road map. Quality improvement tools, customer focus, cost of quality 	8
VII	<ul style="list-style-type: none"> • Food Laws Food Laws and Standards: National and International food laws, Mandatory and voluntary food laws. • FSSAI Indian Food Regulations and Certifications: Food Safety and Standards Act, FSSAI Rules, food adulteration, misbranding, common adulterants in foods, Duties and responsibilities of Food Safety Authorities 	8

Reference Books:

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. InteazAlli. 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.

8. R.E. Hester and R.M.Harrison. 2001. Food Safety and Food Quality. Royal Society of Chemistry, Cambridge, UK.
9. Branen A.L. and Davidson, P.M. 1983. Antimicrobials in Foods. Marcel Dekker, Newyork.
10. Jay J.M. 1986. Modern Food Microbiology. 3rd Edn. VNR, New York.
11. Robinson, R.K. Ed. 1983. Dairy Microbiology. Applied Science, London.

Semester II
Course Code: MBT-201 Genetic Engineering

4 Credits Course
Total Lectures=60

Unit	Topic	No. of lectures
I	<p>Introduction and tools for genetic engineering Impact of genetic engineering in modern society; general requirements for performing a genetic engineering experiment; restriction endonucleases and methylases; DNA ligase, 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 <i>in situ</i> hybridization.</p>	12
II.	<p>Different types of vectors Plasmids; Bacteriophages; M13 mp vectors; PUC19 and Bluescript 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</p>	12
III.	<p>Different types of PCR techniques Principles of PCR: primer design; 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;</p> <p>Sequencing methods: enzymatic DNA sequencing; chemical sequencing of DNA; automated DNA sequencing; RNA sequencing; chemical synthesis of oligonucleotides; mutation detection: SSCP, DGGE, RFLP.</p>	12

IV	<p>Gene manipulation and protein-DNA interaction Insertion of foreign DNA into host cells; transformation, electroporation, transfection; 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; DNasefootprinting; methyl interference assay, chromatin immunoprecipitation.</p>	12
IV	<p>Gene silencing and genome editing technologies 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</p> <p>Genetic diseases-Detection and Diagnosis, Gene therapy – ex vivo, in vivo, gene delivery systems, viral and non viral. DNA marker technology in plants, DNA fingerprinting, Genetically engineered biotherapeutics and vaccines and their manufacturing, Transgenic animals and Bio-pharming.</p>	12

Reference Books:

1. Old, R. W., Primrose, S. B., & Twyman, R. M. (2001). ***Principles of Gene Manipulation: an Introduction to Genetic Engineering***. 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). ***Genomes***(3rd ed.). New York: Garland Science Pub.
4. Selected papers from scientific journals, particularly **Nature & Science**.
5. Technical Literature from Stratagene, Promega, Novagen, New England Biolab etc.

Semester II

Course Code: MBT-202: Bacteriology and Virology

4Credits Course, Total Lectures = 60

Unit	BACTERIOLOGY	No. of Lectures
I	<p>Taxonomy and Diversity of Bacteria: Taxonomy, binomial nomenclature, types of bacterial classification systems, new approaches to 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.</p> <ul style="list-style-type: none"> • Concept of 'unculturable' bacterial diversity. - Strategies for culture of 'unculturable' bacteria • The measurement of microbial diversity, Measures and indices of diversity. • Metabolic Diversity in Bacteria 	8
II	<p>Ultrastructure of Bacteria :</p> <ul style="list-style-type: none"> • 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
III	<p>Extremophiles: Archaea, adaptations in extremophiles, applications in biotechnology</p>	4
IV	<p>Applied Bacteriology:</p> <ul style="list-style-type: none"> • 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: Biofertilizers, Biopesticides, Mass production of biofertilizers and quality control, Role of Agrobacterium • Pre and Probiotics • Bacteriology and environment: Bioremediation (Petroleum and Xenobiotic) • Microbial Fuel Cells • Bioluminescence • Bio surfactants 	8
Savitribai Phule Pune University	Current topics/ recent developments of importance can discussed	26

VIROLOGY		
V	<p>Introduction to viruses: General properties of viruses Morphology and ultrastructure of Viruses, Virus related structures – Viroids and Prions</p> <p>Classification of viruses: ICTV system, Baltimore system</p>	4
VI	<p>Replication of viruses:</p> <ul style="list-style-type: none"> • 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
VII	<p>Bacteriophages:</p> <ul style="list-style-type: none"> • Morphology, Genome organization and Life cycle of lamdaphage, M13 	3
VIII	<p>Cultivation of viruses:</p> <ul style="list-style-type: none"> • 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
IX	<p>Viral Diagnosis:</p> <ul style="list-style-type: none"> • Microscopy, Cultivation, Serological and Molecular methods, Infectivity assays, immunodiagnosis <p>Antivirals:</p> <ul style="list-style-type: none"> • Physical and Chemical agents, Therapeutic agents, Vaccines • Viral Interference and Interferons. Nature and source of interferons, Classification of interferons. 	7
X	<p>Animal, Plant and Poultry viruses:</p> <ul style="list-style-type: none"> • Diseases and Importance with examples • Re-emerging and New emerging viral diseases with example (Influenza, H1N1, SARS, Nipah and Marburg), Current outbreaks 	3

Reference Books:

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. Pearson Education 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),

Semester II
Course Code: MBT-203 Plant Biotechnology

4Credits
Total Lectures=60

Unit	Topic	No. of lectures
I	<i>In vitro</i> propagation methods <ul style="list-style-type: none"> • Micropropagation - Advantages over conventional methods, Stages of micropropagation (stage 0 to stage 4), • Commercial application of micro propagation. • Organogenesis, • Commercial application of micro propagation. • Somatic embryogenesis and artificial seeds. • <i>In vitro</i> androgenesis and its applications, • Protoplast: isolation, fusion somatic hybridization, cybridization and their applications • Production of bio active secondary metabolites by plant tissue culture. • Suspension culture: initiation, growth and application 	12
II	Cryopreservation : <ul style="list-style-type: none"> • Concept, theory and various methods and techniques of cryopreservation of plant culture till its revive back • Applications and Disadvantages of cryopreservation 	7
III	Genetic transformationMethods: <ul style="list-style-type: none"> • Ti plasmid & Ri Plasmid vectors. 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. 	14
IV	Genetic manipulation : Introduction, <ul style="list-style-type: none"> • Transgenic plants for biotic and abiotic stress, • Production of secondary metabolites • Concept of Synthetic Biology for production of bioactive secondary metabolites • Increase in productivity by manipulation of photosynthesis and nitrogen fixation, • molecular farming (improvement in protein, lipids, carbohydrates), vaccines, antibodies, therapeutic proteins, 	13
Approaches to marker-free transgenics • Debate over GM crops		29

V	<p>Marker assisted plant breeding and QTL mapping</p> <ul style="list-style-type: none"> • 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 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 	14
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Reference Books:

1. Chawla HC (2004) – Introduction to plant biotechnology (Science Publ)
2. Davies K (Ed) (2004) – Plant pigments and their manipulation – Annual plant reviews, vol 14 (Blackwell Publ)
3. 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. Vasil IK, Thorpe TA (1994) – Plant cell and tissue culture (Springer)
7. H K Das Textbook of Biotechnology 4th edition
8. Plant Cell and Tissue Culture. A Laboratory manual 1994. Reinert J and Yeoman MM Springer
9. Biotechnology in Crop Improvement, H S Chawla. International Book Distributing Company 1998
10. Practical Application of Plant Molecular Biology. RJ Henry. Chapman and Hall 1997
11. Elements of Biotechnology, P.K. Gupta. Rastogi and Co., Meerut 1996

12. A Text Book of Biotechnology, HD Kumar (WE pub.)
13. Gene transfer to Plants 1995, Polykus I and Spongernberg, G. Ed. Springer Scam.
14. Molecular Approaches to Crop Improvement 1991. Dennis Liwelly Eds. PP 16
15. Plant Biotechnology 1994, Prakash and Perk, Oxford & IBH Publishers Co
16. Plant Cell and Tissue Culture. A Laboratory manual 1994. Reinert J and Yeoman MM Springer.
17. Plant Biotechnology: An Introduction to Genetic Engineering by Adrian Slater, Nigel W. Scott, Mark R. Fowler. Oxford University Press, 2008.
18. 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.
19. Heffner, E.L., M.E. Sorrells, and Jannink, J.-L. 2009. Genomic selection for crop improvement. Crop Sc. 49: 1-12.

Semester II**Course Code: MBt-204 Lab Course II (Genetic Engineering, Bacteriology and Virology, Plant Biotechnology)****4 Credits Course**

Sr .No	List of Practical	No. of Practical
1.	Plasmid DNA isolation and DNA quantitation	1
2.	Restriction Enzyme digestion of plasmid DNA	1
3.	Genetic Transfer-Conjugation, gene mapping	2
4.	Polymerase Chain Reaction and analysis by agarose gel electrophoresis	1
5.	Preparation of competent cells	1
6.	Transformation of <i>E.coli</i> with standard plasmids, Calculation of transformation efficiency.	2
7.	Vector and Insert Ligation	1
8.	Southern hybridization	1
9.	Cleanliness, Good laboratory practices, media preparation, Sterilization of media and glassware	1
10.	Isolation of the following types of bacteria from natural samples. Identification of the bacteria to at least the Genus level using the Bergey's Manuals: Mesophilic bacteria /Thermophiles The identification key must be designed for each isolated and identified bacterium. Students are expected to isolate at least one Genus from each group.	3
11.	Cultivation of Anaerobes (any one method)	1
12.	Propagation of viruses in animals/tissue culture /embryonated eggs.	2

13.	Qualitative and quantitative detection of bacteriophages	1
14.	Animal virus titration by Hemagglutination test	1
15.	Electron microscopic observations of ultrastructure of animal viruses(Pox, Influenza, Rabies and TMV	1
16.	<i>Chlorella</i> or <i>Spirulina</i> culture establishments and study of its growth using suitable parameters	1
17.	<i>In vitro</i> induction of somatic embryogenesis and preparation of artificial seeds	1
18.	Induction of Androgenesis <i>in vitro</i>	1
19.	Protoplast isolation and Fusion from plant material	1
20.	Micropropagation : initiations , multiplication and subculture	2
21.	Initiation of suspension culture and identification of common secondary metabolites production	2
22.	Preservation of in vitro cultures—use of slow growth and low temperature	2
23.	Visit to tissue culture laboratory and report writing	

Semester II**Course Code MBT 205: Clinical Research, Data Management and IPR****4Credits Course****Total Lecture: 60**

Unit	Topic	Number of Lectures
CLINICAL RESEARCH AND DATA MANAGEMENT		
I	Introduction to Clinical Research Drug Development Process <ul style="list-style-type: none"> Overview of Drug Development Process including clinical trials phases 	1
II	Protocol Designing: <ul style="list-style-type: none"> Definition of protocol, its importance and purpose Protocol format: Chapters (Headings) and broad contents of protocol Important scientific and administrative aspect included in protocol Protocol writing team and role of each member Clinical trial design: Types of study designs Sampling, sample size, randomization, Inclusion & Exclusion criteria Phases of clinical trial & Types of trials 	5
III	Good Clinical Practice (GCP)-ICH E6: <ul style="list-style-type: none"> 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 situations Responsibilities of Sponsors, Investigators & Regulators ICH: Purpose, regulations & guidelines Informed consent and Informed consent form Essential Documents 	5
IV	Drug Regulatory Affairs (Clinical Trial) <ul style="list-style-type: none"> Regulatory Authority in India (DCGI & CDSCO) Schedule Y of Drugs & Cosmetics Act International Scenario of Regulatory Aspects: FDA, CFR, 	4

V	Clinical Safety & Pharmacovigilance: <ul style="list-style-type: none"> • Definitions of AE, ADR, SAE, • Recording & reporting: Objectives & Importance • Pharmacovigilance: International procedures • Pharmacovigilance in India 	3
VI	Monitoring of Clinical Trials <ul style="list-style-type: none"> • Monitoring and its role in clinical trials • CRF and other source documents relevant to monitoring 	2
VII	Concept of Database and Clinical Data Management <ul style="list-style-type: none"> • Concept and designing of Database, • Data management & IT in clinical research • CRF designing • Query raising and query resolution • EDC System and 21 CFR Part 11 compliance • Practical for Protocol Design, CRF Design and source documentation 	10
INTELLECTUAL PROPERTY RIGHTS		
VIII	<ul style="list-style-type: none"> • General Regime of Intellectual Property Rights: Overview and Historical Perspectives; • Intellectual Property as an Instrument of Development; • Need for Protecting Intellectual Property- Policy Consideration- National Perspectives and International demands; • TRIPS (Trade Related Intellectual Property Rights) Agreement and International Treaties related to IPR 	6
IX	<ul style="list-style-type: none"> • Patents: Criteria of Patentability; types of patent applications: provisional and complete specifications. • Procedure for Filing Patent Applications, Patent Granting Procedure; • Revocation, Patent Infringement and Remedies; • Relevant Provisions of the Biological Diversity Act, 2002; • Commercialization of patented innovations; licensing – outright sale, licensing, royalty; 	8

X	<ul style="list-style-type: none"> • Copyright and Neighboring Rights - Conceptual Framework, Copyright works, Ownership, transfer and 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; 	12
XI	Patent Specification Drafting Exercise	4

Reference Books:

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/cfcr/cfrsearch.cfm>
6. Karki, M S, Intellectual property rights: basic concepts (2009) M Atlantic Publishers & Distributors, New Delhi
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), 4th edition, Wiley India Pvt. Ltd, New Delhi
10. Chawala, H .S., Introduction to Plant Biotechnology, 3rd edition, Science Publishers
11. Hirvani R, Patents in Plant Breeding: Guarding the Green Gold-,Biotech News, (2009),vol 4.,
12. GanguliPrabuddh, 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 & Trade,(CGPDTM): Manual of Patents/Manual of Industrial Design/Draft Manual of Trademarks
15. Website: <https://www.wipo.int> / www.ipindia.nic.in

Semester II
Course Code: 206 Medical Biotechnology

4 Credits Course

Total Lectures= 60

Unit	Topics	No. of Lectures
I	<p>Introduction to molecular basis of Disease :</p> <ul style="list-style-type: none"> • Introduction, Worldwide market in medical biotechnology, Revolution in diagnostics and therapy. • Introduction to Chromosomal Disorders and Structural Disorders with examples • Classifications of Genetic diseases • Single Gene disorders Sickle cell anaemia and Thalassemia, polygenic diseases eg Type I diabetes, Alzheimer Disease • Infectious disorders 	15
II	<p>Diagnosis:</p> <ul style="list-style-type: none"> • Diagnosis using protein and enzyme markers: Enzyme probes Glucose oxidase, Monoamine oxidase. • Diagnosis using Monoclonal antibodies – hormonal disorders & infectious diseases • DNA/RNA based Diagnosis: PCR based & Use of Nucleic acid probes • Biosensors in clinical diagnosis • Microarray Technology for disease diagnosis • Genetic Counselling 	15
III	<p>Therapies:</p> <ul style="list-style-type: none"> • Gene Therapy: ex vivo & in vivo gene therapy • Strategies of Gene therapy: Gene augmentation, antisense therapy, ribozymes. • Vectors used in gene therapy and synthetic vectors • Gene therapy trials: ADA deficiency, Cystic fibrosis, HIV • Enzyme therapy: Gauchers disease, • Hormone replacement therapy: Diabetes • DNA based Vaccines: Subunit Vaccines and Attenuated Vaccines 	15
IV	<p>Stem Cell Therapy and Nanotechnology:</p> <ul style="list-style-type: none"> • Stem cells in therapy -embryonic & adult stem cells, Characteristics & properties of stem cells. Potential use of stem cells • Cell & Tissue engineering • Bio-artificial organs (liver, Blood cells, skin) • Nanotechnology in diagnosis 	15

Reference Books:

- 1) Introduction to Human Molecular genetics- J J Pasternak, John Willey Publications
- 2) Human Molecular genetics – McConkey
- 3) Medical Biotechnology-PratibhaNallari V Venugopal Rao Oxford Press
- 4) Medical Biotechnology-1st edition- Juditponggracz, Mary Keen
- 5) Medical Biotechnology-by Bernald Glick, Terry L Delovitch, Cheryl L Pattern ASM press 2014.
- 6) Molecular Biotechnology- Principles and Applications of Recombinant DNA, 4th Edition by Bernald Glick Cheryl L Pattern
- 7) Medical Biotechnology first edition by Trivedi P C Avishkar Publisher
- 8) Medical Biotechnology Principle and Applications by Kun L Y world Science Publications.
- 9) Methods of Biotechnology and Bioengineering by Vyas CBS publications 2004
- 10) Stem Cell technology by Marshak et al CSHL publications