



Shri Vile Parle Kelavani Mandal's
**MITHIBAI COLLEGE OF ARTS, CHAUHAN INSTITUTE OF SCIENCE & AMRUTBE
JIVANLAL COLLEGE OF COMMERCE AND ECONOMICS (AUTONOMOUS)**
*NAAC Reaccredited 'A' grade, CGPA: 3.57 (February 2016),
Granted under RUSA, FIST-DST & -Star College Scheme of DBT, Government of India,
Best College (2016-17), University of Mumbai*

Affiliated to the
UNIVERSITY OF MUMBAI

Program: Master of Science

Course: BIOTECHNOLOGY

Semester III and IV

**Choice Based Credit System (CBCS) with effect from the
Academic year 2020 – 2021**

PROGRAMME SPECIFIC OUTCOMES (PSO'S)

On completion of the M.Sc Biotechnology, the learners should be enriched with knowledge and be able to-

- PSO1:** Analyze and interpret scientific data to solve technical, conceptual and abstract scientific problems including prediction and modeling to complex molecular and biotechnological activities.
- PSO2:** Apply knowledge to develop critical thought and practical understanding in the field of biotechnology to find solutions for human benefits in health care, agriculture, environment and related fields.
- PSO3:** Identify and analyze a molecular or biochemical problem and formulate, research literature, review existing knowledge to reach substantiated conclusions using principles of Biotechnology independently or in a team
- PSO4:** Can become entrepreneurs in various basic and applied sectors of biotechnology such as diagnostics, drug designing, stem cell biology, immunology, environmental biotechnology etc.
- PSO5:** Can become entrepreneurs in various demanding sector of biotechnology such as diagnostics, drug designing, stem cell biology, immunology, environmental biotechnology etc
- PSO6:** The student will develop sensitivity to environmental issues and concerns and shall understand principles of ethics within the framework and apply these principles for environmentally and culturally sensitive issues.
- PSO7:** Understand the importance of quality control, bioethics, intellectual property and know the process to file patents in for inventions in the fields of life science

Preamble

Biotechnology is a multidisciplinary field that incorporates the exploitation of knowledge regarding biological processes and the concepts in organisms, cells or cellular components to develop new technologies. The new tools and products developed by biotechnologists are useful in research, agriculture, health care and pharmaceutical industry. Biotechnology is a rapidly developing sector and the advancements made at a good pace. The curriculum is prepared by following the prospectus of various national and international universities and standards of national eligibility tests. The course aims at giving overall knowledge, skill to the students through theoretical, practical and hands on experience to develop scientific endeavours as well as startups. Each student will be a thorough researcher as he/she is trained and guided by scientists / industry experts and gains experience in a Scientific project during his 3-4 months research project at reputed research institutes. The syllabue aims at economic and social renaissance its biomedical and cutting edge technological applications are tremendously powerful in shaping this century and exciting biofuture.

Evaluation Pattern

The performance of the learner will be evaluated in two components. The first component will be a Continuous Assessment with a weightage of 25% of total marks per course. The second component will be a Semester end Examination with a weightage of 75% of the total marks per course. The allocation of marks for the Continuous Assessment and Semester end Examinations is as shown below:

a) Details of Continuous Assessment (CA)

25% of the total marks per course:

Continuous Assessment	Details	Marks
Component 1 (CA-1)	Test / Assignment/ Tutorial/ Visit/ Project/ Presentation	15 marks
Component 2 (CA-2)	Test / Assignment/ Tutorial/ Visit/ Project/ Presentation	10 marks

b) Details of Semester End Examination

75% of the total marks per course. Duration of examination will be two and half hours.

Question Number	Description	Marks	Total Marks
1	Descriptive question from Unit I	15	15
2	Descriptive question from Unit I	15	15
3	Descriptive question from Unit I	15	15
4	Descriptive question from Unit I	15	15
5	Short Notes from Unit I, II, III and IV	15	15
Total Marks			75

Signature

Signature

Signature

HOD

Approved by Vice –Principal

Approved by Principal

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Program: M SC BIOTECHNOLOGY				Semester: III	
Course: MEDICAL MICROBIOLOGY AND BIOTECHNOLOGY				Course Code: PSMABT 305	
Teaching Scheme			Evaluation Scheme		
Lecture (Hours per week)	Practical (Hours per week)	Tutori al (Hour s per week)	Credit	Continuous Assessment (CA) (Marks - 25)	Semester End Examinations (SEE) (Marks- 75 in Question Paper)
4	3		4+2	25	75
Learning Objectives:					
<ol style="list-style-type: none"> 1. To provide the conceptual basis for understanding medically-important bacteria, fungi, parasites and viruses and the clinical concerns and challenges related to them 2. To develop a critical understanding of emerging diseases, current epidemics, pandemics, prevention and control of challenging infectious diseases 					
Course Outcomes:					
At the end of the course the student will be gain knowledge of:					
CO1: The bacteria, fungi, parasites and viruses of medical importance					
CO2: Diseases of pandemic potential; epidemic diseases of critical importance, infection control and bioterrorism					
Outline of Syllabus: (per session plan)					
Module	Description				No of Hours
1	Bacteriology				15 hrs
2	Mycology and Parasitology				15 hrs
3	Virology				15 hrs
4	Emerging Diseases and Management				15 hrs
	Total				60
PRACTICALS					

To develop scientific temper and interest by exposure through industrial visits and study/educational tours is recommended in each semester

PRACTICAL I

(If applicable)

Unit	Topic	No. of Hours/Credits
Module 1	<p>Bacteriology: The Bacteria of Medical Importance The Gram-Positive and Gram-Negative Cocci of Medical Importance The Gram- Positive and Gram- Negative Bacilli of Medical Importance</p> <ul style="list-style-type: none"> ▪ Growth and Physiological Characteristics ▪ Epidemiology and Pathogenesis <p>Treatment and Clinical Concerns</p>	15
Module 2	<p>Mycology and Parasitology: The Fungi of Medical Importance</p> <ul style="list-style-type: none"> ▪ Organization of Fungal Diseases <p>Subcutaneous Mycoses Cutaneous Mycoses Superficial Mycoses Opportunistic Mycoses</p> <ul style="list-style-type: none"> ▪ Growth and Physiological Characteristics ▪ Epidemiology and Pathogenesis ▪ Treatment and Clinical Concerns <p>The Parasites of Medical Importance The Flagellates The Helminthes The Nematodes The Flatworms</p> <ul style="list-style-type: none"> ▪ Life and transmission cycles ▪ Epidemiology and Pathogenesis ▪ Treatment and Clinical Concerns 	15
Module 3	<p>Virology: Viruses That Infect Humans: The DNA Viruses The RNA Viruses</p> <ul style="list-style-type: none"> ▪ Pathogenesis and Disease spectrum ▪ Epidemiology and Treatment <p>Prevention, Control and Clinical Concerns</p>	15
Module 4	<p>Emerging Diseases and Management Emerging diseases and current pandemics Infection control Sentinel Laboratory Response to Bioterrorism</p>	15

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1. Study of life cycle of parasites of medical importance
2. Study of challenges and clinical concerns of bacterial/fungal diseases
3. Case history studies and problem solving approaches to study bacterial/fungal/viral diseases
4. Emerging diseases and current pandemics

Suggested Readings

Text Books:

1. Talaro, K. P., & Chess B. (2012). Foundations in Microbiology (8th ed.) McGraw-Hill, New York
2. Patricia M. Tille (2013) Bailey & Scott's Diagnostic Microbiology (13th Edition) Elsevier
3. Madigan, M. T., Martinko, J. M., Bender, K. S., Buckley, D. H., & Stahl, D. A. (2015). Brock biology of microorganisms (14th edition.). Boston: Pearson.

Reference Books:

1. Goering, R. V., & Mims, C. A. (2008). Mims' Medical Microbiology. Philadelphia, PA: Mosby Elsevier
2. Brooks, G. F., Jawetz, E., Melnick, J. L., & Adelberg, E. A. (2013). Jawetz, Melnick & Adelberg's Medical Microbiology (26th edition.). New York : London: McGraw-Hill Medical

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Program: M.Sc Biotechnology	Semester: II
Course: BIOTECHNOLOGY : RECENT TRENDS AND EMERGING DIMENSIONS	Course Code: PSMABT306

Teaching Scheme				Evaluation Scheme	
Lecture (Hours per week)	Practical (Hours per week)	Tutorial (Hours per week)	Credit	Continuous Assessment (CA) (Marks - 25)	Semester End Examinations (SEE) (Marks- 75 in Question Paper)
4	4	-	4+2	25	75

Learning Objectives:

1. To provide students with a sound coverage of human reproductive biology within the framework of Human Biology and also provides an important foundation to consider sexual differentiation and development, contraception, infertility and current reproductive technologies.
2. This course also introduces the fundamentals of nanoscience and its current and future applications with respect to their impact in commercial products and technologies.
3. Nutritional genomics offers great promise to personal health management based on the understanding of the relationship between diet, gene expression and health outcomes.
4. Introduction to Green Technology offers students a real world opportunity to discover and understand principles of physics, engineering, design and green-clean technologies for generating energy to non-toxic cleaning products.

Course Outcome:

- CO1.** Students will have gained an overall understanding of human reproduction, its associated technologies and emerging trends in developmental biology
- CO2.** Nanotechnology unit will offer globally-relevant, industry-linked, research-focused, technology-enabled seamless education at the postgraduate and research levels which provide relevant knowledge about fundamental principles of nanotechnology and their application to medicine, healthcare, environment and biomedical and cosmetic industries to achieve the global technological needs.
- CO3.** Nutrigenomics is the application of high-throughput genomics tools in nutrition research. It will promote an increased understanding of how nutrition influences metabolic pathways and homeostatic control. Students will be able to demonstrate the appreciation for the methods and strategies used to study complex trait genetics and nutrition.
- CO4.** Develop a thorough understanding of the concepts of sustainability and cleaner production, and the challenges that engineers face in applying these concepts in an industrial and societal context.

Outline of Syllabus: (per session plan)

Module	Description	No of Hours
1	Reproductive Biotechnology	15

2	Current Trends in Nanotechnology	15
3	Foodomics	15
4	Green Technology	15
	Total	60
PRACTICALS		

PRACTICALS:

1. Study of culture systems and embryo transfer techniques used in Assisted reproductive technology
2. Study of the new technological applications and societal implications in the field of nanotechnology
3. Study on recent trends in Nutrigenomics - Opportunities and Challenges
4. Report on GM Crops: Boon or Bio-hazard?
5. Report on emerging green technologies in India.

Suggested Readings

Text Books:

1. Textbook of Assisted Reproductive Techniques Laboratory and Clinical Perspectives Second Edition by David K Gardner, Ariel Weissman
2. Nanotechnology by M.H Fulekar
3. Nanotechnologies: Principles, Applications, Implications and Hands-on Activities. A compendium for educators by Luisa Filipponi and Duncan Sutherland
4. Biotechnology –Recent trends and emerging dimensions- –Atul Bhargava
5. Environmental biotechnology—Indu shekhar thakur
6. Environmental biotechnology—M.H fulekar
7. Textbook of Biotechnology (2005) R. C. Dubey S. Chand and Co.

Reference Books:

1. Developmental Biology (8th Edition 2006) Scott F. Gilbert Sinauer Associates, Inc.

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Program: M.Sc Biotechnology	Semester: III
Course: : Drug Development, design and Clinical studies	Course Code: PSMABT307

Unit	Topic	No. of Hours/ Credits
Module 1	<p>Reproductive Biotechnology Handling and Preparation of the Sperm and Oocytes Preparation and evaluation of sperm Preparation and evaluation of oocytes for intracytoplasmic sperm injection Oocyte in vitro maturation Micromanipulation Equipment and general technical aspects of micromanipulation of gametes and embryos Culture systems and transfer techniques for the human embryo Cryopreservation of Gametes, Embryos and Spermatozoa Infertility and reproductive vaccines.</p>	15
Module 2	<p>Current Trends in Nanotechnology Applications and implications: Medicine and healthcare sector-diagnosis, therapy and regenerative medicines. Nanoparticles- drug delivery and drug delivery systems Surgical techniques and innovations Environment -Remediation and protection, pollution prevention, environment sensing Cosmetics industry-formulations, Nano cosmetics, Benefits vs risks</p>	15
Module 3	<p>Foodomics Nutrigenomics: the future of human health The Nutrigenomics Science Tools and Techniques for Nutrigenomics Research Important Initiatives in Nutrigenomics Research Development The Human Variome Project The Nutritional Phenotype Database The Nutrigenomics Organization The HapMap Project Advantages of Nutrigenomics Issues, Uncertainties, and Risks Opportunities and Challenges Future of Nutrigenomics</p>	15
Module 4	<p>Green Technology Biofuels- Types of biofuels Solid biofuels Liquid biofuels Gas biofuels Bio pesticides-</p>	15

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	Types of Bio pesticides Mode of action Advantages and disadvantages of microbial insecticides Bio fertilizers- Types of Bio Fertilizers-Bacterial, Fungal and Algal Biosorption- Microorganisms in metal absorption Mechanisms in bio absorption Factors affecting bio absorption Bioreactors in bio absorption	
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Teaching Scheme				Evaluation Scheme	
Lecture (Hours per week)	Practical (Hours per week)	Tutorial (Hours per week)	Credit	Continuous Assessment (CA) (Marks - 25)	Semester End Examinations (SEE) (Marks- 75 in Question Paper)
4	4		4+2	25	75

Learning Objectives:

- To give a broad overview of research and development carried out in industrial setup towards drug discovery.
- To enable the students to conceptualize the process of the drug development from laboratory to market and consumer,
- Give overall information on different safety procedures taken as good laboratory techniques for the safe drug development

Course Outcomes:

After completion of the course, learners would be able to:

CO 1: to understand basics of R&D in drug discovery

CO2: to apply knowledge gained in respective fields of pharmaceutical industry

Outline of Syllabus: (per session plan)

Module	Description	No of Hours
1	Drugs discovery process	15
2	Drug-pre clinical toxicology	15
3	Clinical safety	15
4	Drugs- regulatory affairs-Reporting	15
	Total	60

PRACTICALS

Unit	Topic	No. of Hours/Credits
<p>Module 1</p>	<p>The Drug Discovery Process: Some Challenges for Modern Drug Discovery, Target-Based Drug Discovery; Systems-Based Drug Discovery ; In vivo Systems, Biomarkers, and Clinical Feedback Types of Therapeutically Active Ligands: Polypharmacology Pharmacology in Drug Discovery, Chemical Sources for Potential Drugs; Pharmacodynamics and High-Throughput Screening; Drug Development; Structure based drug development: Drug Molecular docking- Types and principles, Ligand-based drug development: Pharmacophore modeling, Principles & mechanisms of drug action; Pharmacokinetics & pharmacodynamics; Types of drugs, Routes of administration, Principles of drug absorption, drug metabolism and distribution - intestinal absorption, metabolic stability, drug-drug interactions, plasma protein binding assays, metabolite profile studies</p>	<p>15</p>
<p>Module 2</p>	<p>Clinical Testing Identification of relevant groups on a molecule that interact with a receptor and are responsible for biological activity; Understanding structure activity relationship; Structure modification to increase potency and therapeutic index; Concept of quantitative drug design Quantitative structure–activity relationship models (QSAR models) Objectives of Phase I, II, III and IV clinical studies, Clinical study Design, blinding, enrollment, sites and documentation Principles of toxicology, Experimental design for preclinical and clinical PK/PD/TK studies, Pre-clinical toxicology studies, Preclinical toxicology: General principles Systemic toxicology -single and repeat dose toxicity studies Carcinogenicity, mutagenicity and teratogenicity studies Reproductive toxicity, local toxicity and genotoxicity studies Animal toxicity requirements Selection of animal model; Regulatory guidelines for preclinical PK/ PD/TK studies; Statistical analysis and documentation</p>	<p>15</p>

PRACTICAL I

Module 3	<p>Clinical safety studies: Scope of GLP, SOP for conduct of clinical & non clinical testing, control on animal house, report preparation and documentation Integration of non-clinical and preclinical data to aid design of clinical studies.</p> <p>Drug Toxicity- OECD guidelines Acute, sub-acute and chronic toxicity studies , Carcinogenicity, teratogenicity, genotoxicity, mutagenicity, Definition of Toxicological Dose Descriptors (LD50, LC50, EC50, NOAEL, LOAEL, NOEC, DT50) Requirements of GMP implementation, Documentation of GMP practices, CoA, Regulatory certification GMP, Quality control and Quality assurance, concept and philosophy of TQM, ICH and ISO 9000; ICH guidelines for Manufacturing, Understanding Impurity Qualification Data, Stability Studies.</p>	15
Module 4	<p>Global Regulatory Affairs and different steps involved, Regulatory Objectives, Regulatory Agencies; FDA guidelines on IND and NDA submissions, Studies required for IND and NDA submissions for oncology, HIV, cardiovascular indications, On-label vs. off-label drug use GCP and Requirements of GCP Compliance, Herbal drugs- regulatory issues with herbal drugs, regulatory requirement in herbal drugs in India</p> <p>Ethical issues and Compliance to current ethical guidelines, Ethical Committees and their set up, Animal Ethical issues and compliance. Clinical study reports Principle and software in clinical data management Medical writing: Medical articles, abstracts, publications IMRAD (Literature search, bibliography) Contract writing</p>	15

1. 1. Quantification and assimilation estimation of drugs
2. Efficiency of the Drug after expiry- antibiotic
3. Testing of combination drugs
4. QA-QC analysis of drug composition.
5. Comparison of synthetic and traditional drug efficacies

Suggested Readings

1. Krogsgaard-Larsen et al. Textbook of Drug Design and Discovery. 4th Edition. CRC Press.
2. Nally, J. D. (2006) GMP for Pharmaceuticals. 6th edition. CRC Press
3. Brody, T. (2016) Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines. Academic Press.
4. Yan Q, (2008), Pharmacogenomics in Drug Discovery and Development, Springer-Verlag New York, LLC.
5. Meyer UA and Tyndale RF, (2005), Pharmacogenomics, 2nd Edition, CRC Press.

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6. Innocenti F, (2005), Pharmacogenomics: Methods and Applications, Springer-VerlagNew York, LLC.
7. Rothstein MA and Collins FS, (2003), Pharmacogenomics: Social, Ethical, and Clinical Dimensions, Wiley John & Sons, Inc.

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Program: M.Sc. Biotechnology				Semester: III	
Course: Quality Management, Biosafety and Entrepreneurship				Course Code: PSMABT308	
Teaching Scheme				Evaluation Scheme	
Lecture (Hours per week)	Practical (Hours per week)	Tutorial (Hours per week)	Credit	Continuous Assessment (CA) (Marks - 25)	Semester End Examinations (SEE) (Marks- 75 in Question Paper)
04	02		04 + 02	25	75
Learning Objectives:					
<ul style="list-style-type: none"> i. To understand the concept of Quality Assurance and good manufacturing as well as good laboratory practices in the context of modern biotechnology, ii. To give an idea of various quality certification standards good laboratory and manufacturing practices, iii. To develop the concept of bioethics, biosafety and risk assessment, iv. To make students capable of using their knowledge to become future entrepreneur v. To focus on biodiversity conservation, laws related to it. 					
Course Outcomes:					
<ul style="list-style-type: none"> i. Get the knowledge of quality assurance and quality control in the field of biotechnology, ii. Get an idea of biosafety guidelines, regulatory laws for transgenic organisms iii. Aware of effects of release of GMOs, environmental impact assessment iv. Get acquainted with entrepreneurship options in the field of biotechnology and government policies v. Know about legal aspects of biodiversity conservation at national and international levels 					
Outline of Syllabus: (per session plan)					
Module	Description				No of Hours
1	QA QC GLP				15
2	Biosafety And Risk Assessment				15
3	Bioentrepreneurship				15
4	Biodiversity & Environmental laws				15
	Total				60
PRACTICALS					

**PRACTICAL I
(If applicable)**

1. SOP for laboratory instruments

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2. Calibration of glassware and instruments Report on planning of establishing a hypothetical biotechnology industry in India
3. Case study on clinical trials of drugs in India with emphasis on ethical issues.

Unit		No. of Hours/Credits
Module 1	<p>QA QC GLP Quality Assurance and Quality Control- Types of Quality Testing (models, types, procedures etc.);</p> <p>Quality Testing Tools and Techniques Quality Certifications, Govt. Regulations, ICH Guidelines and ISO 9000</p> <p>Quality Assurance, Quality control, Management of QA, QC, Quality Assurance and Quality Control in pharmaceutical and healthcare industries, Validation.</p> <p>Total Quality Management and GMP, Role of Quality Control Checks, Inspections and Audits; GLP and their role in maintenance of QA and QC.</p> <p>Quality assurance and validation: concept, documentation – SOPs</p>	15 Hours
Module 2	<p>Biosafety And Risk Assessment</p> <p>Biosafety: Introduction; Historical Background; Biological Safety Cabinets; Primary Containment for Biohazards; Biosafety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals;</p> <p>Biosafety guidelines - Government of India; Definition of GMOs & LMOs; Roles of Institutional Biosafety Committee, RCGM, GEAC etc. for GMO applications in food and agriculture;</p> <p>Risk Assessment; Risk management and communication; Overview of National Regulations and relevant International Agreements including Cartagena Protocol</p> <p>Environmental release of GMOs; Risk Analysis, Safety and Environment Impact concerns with respect to GMOs, regulatory guidelines in the use of GM foods, Crops and Livestock, ethical concerns in the use of GMOs</p>	15 Hours
Module 3	<p>Bioentrepreneurship</p> <p>Introduction, Importance, Scope, Growth of a biotech company, biotech business model, business plan and funding, business strategies, collaborations, technology transfer.</p>	15 Hours

4. Case study on handling and disposal of radioactive waste

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	<p>Skills for successful entrepreneur, advantages of being entrepreneur, Business concept, types of bio-industries, bio-entrepreneurship in different countries;</p> <p>Marketing Management for Agri Business, Opportunities for agri-entrepreneurship and rural enterprise</p> <p>Bioentrepreneurship in India-development programmes by various agencies, protection & commercialization strategies, funding agencies, International market, Patent landscape</p>	
Module 4	<p>Biodiversity & Environmental laws Biodiversity Conservation strategies, Climate change and conservation of genetic resources; International treaties relating to Biodiversity.</p> <p>Biodiversity Legislation in India; Indian Biodiversity Act and provisions, Biodiversity Act 2002; Agricultural biodiversity; International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA); Impact of GE crops on Biodiversity.</p> <p>Functions of International union for the protection of new varieties of plants (UPOV); International treaties relating to Biodiversity.</p> <p>National bureaus of genetic resources: Establishment, Research Network and activities of NBPGR, NBAGR, NBAIM, NBFGR, NBAII. National Forest Policy, National water Policy, Reclamation of wastelands, Development of environmentally friendly processes such as integrated waste management, bioplastics, biofuel production</p> <p>Environmental impact assessment; Principles of Assessment, Meaning and concept, Methods Around the world and Transboundary application of plants.</p>	15 Hours
TOTAL	Total	60 Hours

5. Study of all the biotic and abiotic components of any simple ecosystem- natural pond or terrestrial ecosystem or human modified ecosystem.
6. Principles of environmental audit & case studies on environmental impact assessment
7. Study any five endangered/ threatened species- one from each class

Suggested Readings:

Text Books:

1. S. N. Jogdand, Entrepreneurship and business of Biotechnology, Himalaya Publishing House, 2007.
2. Environmental Biotechnology – Phulekar, CRC Press

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3. Alexandra George (2006) Globalisation and Intellectual Property, Ashgate publishing company
4. Maarten Bode, (2008) Taking traditional knowledge to the market, Orient Longman Publishers
5. Poornima M Charanthmath , “Entrepreneurship Development – small Business Enterprises”, Pearson Education – 2005
6. S S Khanka , Entrepreneurship Development; S Chand
7. Desai, Vasant: The dynamics of entrepreneurial development and management : Planning for future sustainable growth. (5th edition) Mumbai. Himalaya Publishing House, 2009.
8. Das M.K & Choudhury B.P. 2008. A Text book on Plant Nomenclature and Biodiversity Conservation. Kalyani Publishers.
9. Hopsetti BB. & Venketashwarlaru M. 2001. Trends in Wild Life Conservation and Management. Vol. 2, Daya Publishing House, New Delhi.
10. Murugesan, A.G. & Rajakumari, C.: Environmental science and biotechnology : Theory and techniques. Chennai. MJP Publishers, 2006.
11. Scragg, Alan: Environmental biotechnology. (Reprint) Oxford. Oxford University Press, 2005 (2011).
12. Glick, Bernard R., Pasternak, Jack J. & Patten, Cheryl L.: Molecular biotechnology : principles and applications of recombinant DNA. (4th ed.) Washington, D.C., ASM Press, 2010.
13. Evans, Gareth M. & Furlong, Judith C.: Environmental biotechnology: theory and application. (2nd ed.) New Delhi. Wiley India Pvt. Ltd., 2011(2013).
14. Handbook of Environmental management and technology, Wiley Intersciences Publishers
15. InduShekhar Thakur (2006) Environmental Biotechnology: Basic Concepts and Applications, I. K. International Pvt Ltd, 2006
16. Burke, Gwendolyn, Singh, Ben Ramnarine & Theodore, Louis: Handbook of environmental management and technology. (2nd ed.) New York. John Wiley & Sons, 2000.
17. Biosafety in Microbiology and biomedical laboratories, 5th Ed. (2009): CDC, NIH publication. HHS publication (21-1112)
18. <http://dbtbiosafety.nic.in>
19. Humberto Vega-Mercado, Michael Dekleva, Rizwan Sharnez, and Luis Baez, May 2003, HACCP: A Process Validation Tool for Ensuring Quality of Biotech and Pharmaceutical Products, Bioprocess technology
20. N. Alexandrova, K. Georgieva & A. Atanassov (2005) Biosafety Regulations of GMOS: National and International Aspects and Regional Cooperation, Biotechnology & Biotechnological Equipment, 19:sup3, 153-172.
21. Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal.
22. Traavik. T and Lim Li Ching, (2007): Biosafety first. Tapir Academic Press

Reference Books:

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1. Ratledge, Colin & Kristiansen, Bjorn: Basic Biotechnology. [ed. by] (3rd ed.)
Cambridge University Press, 2006. 978-0-521-72947-5
2. David Pressman (2016) Patent It Yourself 18th edition, Nolo Publishers
3. Ganguli, Prabuddha: Intellectual property rights : unleashing the knowledge economy.
New Delhi. Tata Mcgraw-Hill Publishing Company Limited, 2001. 0-07-
463860-2
4. Sudeep Chaudhuri (2005), the WTO and India's Pharmaceutical industry, Oxford
University Press.
5. Vandana Shiva (2002), Protect or Plunder? Understanding Intellectual Property
Rights, Zed Books

Name of Course: BIOTECHNOLOGY

Course Code: PSMABT

Guide lines to carryout Project work in Semester III

The main purpose of induction of project work at MSc part II is to make the students familiar with Research methodology and the research tools that they have learnt at undergraduate and post graduate level in addition to the scientific writing and expression skills in a methodical manner. The students of Biotechnology require these skills for their better future and employment skills. It will make them to have hands on experience and explore the choices of job opportunities which will increase their employability.

Duration of the project work:

Development on a research problem and the infrastructure available in the department or Research Institutions or Industries, the duration of project work is recommended as follows 06 months : from May 01 to October 31 of the given calendar year (the project work will commence immediately after the conclusion of the semester II of MSc Part I on April 30 of given academic year) 03 months : From May 01 to July 31 or from mid June to mid-September (Either in summer vacation upto July31 of semester III or immediately after commencement of semester III in mid June to mid September (either in summer vacation upto July 31 of semester III or immediately after the commencement of semester III in mid June to mid September.

Each student shall complete a small research project during his academic year of MSc part II. However, the initial reference work can be started in MSc part-I and summer vacation to MSc part II

Nature of the Project:

a. Following will be considered as research Project

Experimental based involving laboratory analytical work with any recognized institution/ M.Sc. research guide/ hospital comprising Industrial training, hands on training in instrumental analytical techniques which they have learnt in their postgraduate courses, covering pharmaceutical, nano technology, cosmetology tissue culture techniques, genetic engineering, medical diagnostics, medical biotechnology, environmental biotechnology, marine biotechnology etc.,

b. Schedule and submission of project work;

Project should be submitted 15 days before the exam

A copy of synopsis should be submitted 15 days before.

2 copies of project work final report duly signed by the research guide, Head of the department should be submitted at the time of the examination.

- The project should contain 80-100 pages covering
- Certificate of completion of project work from the guide
- Certificate of completion of project by HOD
- Student self declaration with reference to plagiarism
- Acknowledgement
- Contents: Introduction, literature survey, material and methods, results, discussion and conclusion
- Bibliography

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Program: MSC BIOTECHNOLOGY				Semester: IV	
Course: Medical Biotechnology				Course Code: PSMABT 405	
Teaching Scheme				Evaluation Scheme	
Lecture (Hours per week)	Practical (Hours per week)	Tutorial (Hours per week)	Credit	Continuous Assessment (CA) (Marks - 25)	Semester End Examinations (SEE) (Marks- 75 in Question Paper)
4	4		4+2	25	75
Learning Objectives:					
<p>1.To develop an understanding of diagnostic methods, procedures and their applications</p> <p>2. To develop an understanding of the basics of vaccine design, including immunologic basis of vaccine efficacy, types of vaccines, and vaccine-associated immunity.</p>					
Course Outcomes:					
<p>At the end of the course the student will be gain knowledge of:</p> <p>CO1: The fundamental principles, strategies and explores the use of different medical diagnostics techniques in the diagnosis of infectious disease.</p>					
Outline of Syllabus: (per session plan)					
Module	Description				No of Hours
1	Approaches to Diagnosis of Infectious Diseases- I				15
2	Approaches to Diagnosis of Infectious Diseases - II				15
3	Approaches to Diagnosis of Infectious Diseases-III				15
4	Vaccines				15
	Total				60
PRACTICALS					

**PRACTICAL I
(If applicable)**

1. Diagnosis of infectious diseases in bacteria
2. Diagnosis of infectious diseases in fungi
3. Diagnosis of infectious diseases in viruses
4. Nucleic acid based methods for diagnosis of infectious diseases
5. Serological and immunological methods for diagnosis of infectious diseases
6. Study of vaccines

Suggested Readings

Unit	Topic	No. of Hours/Credits
Module 1	Approaches to Diagnosis of Infectious Diseases- I Identification Methods and Strategies in Bacteriology Identification Methods and Strategies in Mycology Identification Methods and Strategies in Virology	15
Module 2	Approaches to Diagnosis of Infectious Diseases - II Nucleic Acid-Based Analytic Methods for Microbial Identification and Characterization Hybridization Amplification Sequencing and Enzymatic digestion Post-amplification and Traditional analysis	15
Module 3	Approaches to Diagnosis of Infectious Diseases-III Immunochemical Methods Used for Organism Detection Precipitation tests Particle agglutination tests Immunofluorescence assays Enzyme immunoassays. Serologic Diagnosis of Infectious Diseases Production of antibodies Separating IgM from IgG for serologic testing Methods of antibody detection	15
Module 4	Vaccines Subunit Vaccines Peptide Vaccines Dendritic Cell Vaccines DNA Vaccines Delivery and Immune Mechanisms of Action Improved Efficacy and Immunogenicity Attenuated Vaccines Vector Vaccines Vaccines Directed against Viruses Vaccines Directed against Bacteria Bacteria as Antigen Delivery Systems Adjuvants Systems Biology and Evaluation of Vaccines	15

1. Patricia M. Tille (2013) Bailey & Scott's Diagnostic Microbiology (13th Edition) Elsevier
2. Bernard R. Glick Terry L. Delovitch Cheryl L. Patten (2014) Medical Biotechnology ASM press,

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Program: MSC BIOTECHNOLOGY				Semester: IV	
Course: Culture Techniques and Genetic Engineering				Course Code: PSMABT 406	
Teaching Scheme			Evaluation Scheme		
Lecture (Hours per week)	Practical (Hours per week)	Tutorial (Hours per week)	Credit	Continuous Assessment (CA) (Marks - 25)	Semester End Examinations (SEE) (Marks- 75 in Question Paper)
4	4		4+2	25	75
Learning Objectives:					
<ol style="list-style-type: none"> 1. To introduce students to the principles, practices and application of animal biotechnology, tissue culture, and animal genomics, genetic transformation. 2. To give an idea of advances in plant tissue culture with its commercial aspects and cryopreservation techniques 3. To study gene flow in plants, the commercial aspects of transgenic plants and their applications 					
Course Outcomes:					
At the end of the course the student will:					
CO1: Gain fundamental knowledge in animal biotechnology					
CO2: Gain knowledge in the initiation of primary culture, culturing on a large scale and their applications.					
CO3: Understand the importance of animal cell culture in different applications					
CO4: Able to carry out successful and specialized plant tissue culture and cryopreservation					
CO5: Gain knowledge of marker assisted breeding as well as use of plants as vaccines					
Outline of Syllabus: (per session plan)					
Module	Description				No of Hours
1	Advances in Animal cell culture				15
2	Animal cell technology -applications				15
3	Advanced Techniques in PTC				15
4	Plant Genetic Engineering				15
	Total				60
PRACTICALS					

**PRACTICAL I
(If applicable)**

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1. Count cells of an animal tissue culture suspension and check their viability.
2. Prepare culture media with various supplements for animal tissue culture.

Unit	Topic	No. of Hours/Credits
Module 1	<p>Animal cell culture Laboratory design layout: cell culture media and reagents; culture of mammalian cells, tissues and organs; primary culture, secondary culture, continuous cell lines, suspension cultures; stem cell cultures, cancer cell cultures-spheroids,</p> <p>Types and routes of contamination, growth parameters; Quantitation –cell counting and cell weight; phases of growth cycle-cell cycle with check points;</p> <p>Cell culture reactors; Scale-up in suspension; Rotating chambers; Perfused suspension cultures; Fluidized bed reactors for suspension culture; Scale-up in monolayers;</p> <p>Multisurface propagators; Multiarray disks, spirals and tubes; Roller culture; Microcarriers; Perfused monolayer cultures; Membrane perfusion; Hollow fibre perfusion; Matrix perfusion; Microencapsulation; Growth monitoring.</p> <p>Specialized cell cultures; contamination, controls; Concept of tissue engineering and regenerative medicine</p>	15
Module 2	<p>Animal cell technology – Applications In-vitro fertilization in humans, wild animals and cattle, embryo transfer in wild animals and cattle, applications of embryo transfer technology, story of Noori, Garima, etc; Ovum pick-up and applications of animal cloning Transgenic animals in agriculture and research models</p> <p>Animal cloning - basic concept, cloning for conservation for conservation endangered species; hazards of artificial breeding</p> <p>Animal forensics: Animal species identification in religious disputes, adulteration of meat, theft of farm animals and pets etc., advantages, disadvantages and limitations of DNA forensics.</p> <p>Human and animal health: conventional methods of animal vaccine production, Application of animal cell culture for virus isolation and in vitro testing of drugs, Testing of toxicity of environmental pollutants in cell culture</p> <p>Clinical applications of stem cells: e.g. ACT and London Eye project: retinal pigmented epithelium, Cancer stem cells,</p>	15

3. Prepare single cell suspension from spleen and thymus.

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<p>Module 3</p>	<p>Advanced techniques in PTC: Protoplast isolation, culture and regeneration and usage; Protoplast fusion; Somatic hybrids; Cybrids – biochemical method, auxotrophic mutant selection method, visual selection, applications, somaclonal variation; androgenesis, applications in genetics and plant breeding;</p> <p>Somatic embryogenesis and encapsulated artificial seeds, methods, types, factors influencing somatic embryogenesis, advantages.</p> <p>Anther and pollen culture, production of monoploid plants, triploid plants, ovary culture, embryo culture, embryo rescue.</p> <p>Commercial aspects of tissue culture – for forestry, floriculture, large scale cultivation of economically important plants, Soilless growth of plants and green house technology</p> <p>Cryopreservation: Principle, types, methods. Plant germplasm conservation, Germplasm bank</p>	<p align="center">15</p>
<p>Module 4</p>	<p>Plant Genetic Engineering: Organization of a typical plant gene, transcription start site, reporter, marker genes, promoter genes,</p> <p>Methods for transformation, - satellite RNA and its use in transformation.</p> <p>Gene flow in plants: Marker Assisted Selection (MAS), organelle genome and markers, screening and validation;</p> <p>QTL mapping; Gene pyramiding, Marker Assisted Breeding for various traits. Strategies for Introducing genes of biotic and abiotic stress resistance in plants</p> <p>Commercial status of transgenic plants: Herbicide resistance – microbial EPSP synthase, EPSP resistant GM plants, Virus resistant plants, expression of viral genes,</p> <p>Protease inhibitor, GNA and other lectins; a-amylase inhibitor; nematode resistance.</p> <p>Improved seed storage proteins; Improving and altering the composition of starch and plant oils</p> <p>Molecular plantibodies, plant based expression systems, plant based vaccines.</p>	<p align="center">15</p>

4. Isolate DNA from animal tissue by SDS method.
5. Study of animal cell fusion using PEG.
6. Primary culture initiation from tissues and cultures and development of cell line.
7. Protoplast isolation from plant tissue

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8. Protoplast culture
9. Somatic embryogenesis and production of synthetic seeds
10. Anther and Pollen grain culture
11. PCR to identify GM plants
12. Soilless growth of plants -HYDROPONICS

Suggested Readings

Text Books:

1. Rudin N & Inman K. (2002). An Introduction to Forensic DNA Analysis. 2nd Ed. CRC Press.
2. Pörtner, R. (2007). Animal Cell Biotechnology: Methods and Protocols. Totowa, NJ: Humana Press.
3. Glick, B. R., & Pasternak, J. J. (2010). Molecular Biotechnology: Principles and Applications of Recombinant DNA. Washington, D.C.: ASM Press.
4. An Introduction to Plant Tissue Culture (2007) – Kalyan Kumar Dey, New Central Book Agency
5. Brown, T. A. (2006). Gene Cloning and DNA Analysis: an Introduction. Oxford: Blackwell Pub.
6. Primrose, S. B., & Twyman, R. M. (2006). Principles of Gene Manipulation
7. Freshney, R. I (2010). Culture of Animal Cells. John Wiley and Sons Inc.

Reference Books:

1. D Bailey, (2016), Practical Veterinary Forensics, UK
2. Lincoln PJ & Thomson J. (1998). Forensic DNA Profiling Protocols. Humana Press.
3. Genomics. Malden, MA: Blackwell Pub

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Program: Master of Science (Biotechnology)				Semester : 4	
Course :Environmental Biotechnology and Sustainable Development				Course	Code:
				PSMABT407	
Teaching Scheme			Evaluation Scheme		
Lecture (Hours per week)	Practical (Hours per week)	Tutorial (Hours per week)	Credit	Continuous Assessment (CA) (Marks - 25)	Semester End Examinations (SEE) (Marks- 75 in Question Paper)
4	4		4+2	25	75
Learning Objectives:					
<ol style="list-style-type: none"> 1. Environmental biotechnology is a fundamental component required to address environmental problems. 2. This course includes several topics pertaining with solutions to certain difficult environmental problems. 3. The course covers important topics with respect to current trends in biotechnology, such as treatment and disposal of solid waste and its management. 4. The course deals with recent developments for monitoring and restoring the environment employing biotechnology through biological detoxification, remediation and ecofriendly substitutes for specific pollution problems. 5. This course explores the nature, scope and role of environmental management, with a strong focus on sustainable development through environmental policy, planning and implementation of biotechnology. 					
Course Outcomes:					
After completion of the course, learners would be able to:					
CO1: Existing and emerging technologies for solid waste management and degradation of natural and xenobiotic compounds					
CO2: The modern trends in environmental biotechnology, such as novel applications of biological systems in mining, hydrometallurgy and ecofriendly solutions of higher efficiency for a few industrial processes					
CO3: Environmental management approaches and develop an ability to analyze environmental management in relation to the major principles of sustainable development					
CO4: Theoretical and conceptual issues relating to environment and implement appropriate process for controlling any potential negative impact on the environment by industries					

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Outline of Syllabus: (per session plan)		
Module	Description	No of Hours
1	Hazardous, medical and e-waste management	15
2	Clean up Technology	15
3	Integrated Applications:	15
4	Environmental management for sustainable development	15
	Total	60
PRACTICALS		
Unit	Topic	No. of Hours/Credits
Module 1	Hazardous, medical and e-waste management: Solid waste Types of solid waste Waste monitoring Management of Solid waste Treatment and Disposal Non-hazardous solid Waste Methods and biodegradation Management of non-degradable solid waste Medical solid waste management Evaluation, processing, disposal and geneal remedial measures Hazardous waste management Electronic waste management Components , treatment options , technologies in India	15
Module 2	Clean up Technology: Eutrophication and biological control Algal blooms Removal of phosphorus and nitrogen Biodegradation Aerobic vs Anaerobic Testing for biodegradability Biodegradation and bioconversion of natural compounds Bioconversion and bio utilization of effluent for products Biomethanation Biodegradation and bioconversion of Xenobiotic compounds Factors influencing biodegradability Persistence of Xenobiotics Biodegradation of Hydrocarbons	15
Module 3	Integrated Applications: Pollution monitoring Indicators of pollution	15

	<p>Detection of pollutants – Biosensors Bio Hydrometallurgy and Bio Mining Bioleaching Sulphur Removal from Acid Mine Drainage, Cyanide Removal, Coal-tar Distillation Bio Quenching of Toxic Metal Biosorption– Biosorption of Heavy Metals Biosorbents - Microbial Groups Bacteria, Fungi, Algae, Macrophytes Remedial techniques for specific pollution problems Biopulping Biofiltration Biodegradation of Polymers Bioremediation of crude oil spills</p>	
Module 4	<p>Environmental management for sustainable development: Environmental management fundamentals and goals Process and goals Challenges Approaches to environmental management Sustainable development Ecological concepts and parameters Environmental system and ecosystem planning and management Environmentalism and the Green Movement Participants in environmental management Environmental management and business ‘Greening’ of economics Business Charter for Sustainable Development Measuring sustainable development Standards, indicators and benchmarks Eco-audit Ecological foot-printing Environmental Hazard and risk management Environmental impact assessment Global challenges and Role of Biotechnology</p>	15

**PRACTICAL I
(If applicable)**

1. Determination of BOD
2. Determination of COD
3. Study of bioremediation
4. Enrichment and isolation of phosphate solubilizers
5. Enrichment and isolation degraders of natural compounds (any one)
6. Enrichment and isolation of nitrifying bacteria
7. Study of nitrification
8. Case study for Integrated approaches, environmental management and sustainable development

Suggested Readings

1. Environmental Biotechnology - Theory and Application – M.H. Fulekar: CRC Press and Science Publisher, USA
2. Environmental Biotechnology: Basic Concepts and Applications. 2006, Indu Shekhar Thakur, I. K. International Pvt Ltd
3. Environmental Biotechnology Allan Scragg Oxford University press
4. Environmental Biotechnology S.D. Jogdand Himalaya Publishing (Industrial pollution management) House
5. Introduction to Environmental biotechnology, A. K. Chatterji (2011), PHI Learning private limited, New Delhi.
6. Environmental management for sustainable development , C.J. Barrow. – 2nd ed. Taylor & Francis e-Library, 2006
7. Environment and Sustainable Development. Fulekar, M. & Pathak, Bhawana & Kale, R, Springer, 2014
8. Environmental Microbiology R.M Maier, I.L. Pepper and C. P. Gerba, Academic Press. (2000)

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Program: M. Sc	Semester: IV
Course: : INTELLECTUAL PROPERTY RIGHTS AND BIOETHICS	Course Code: PSMABT408

Teaching Scheme				Evaluation Scheme	
Lecture (Hours per week)	Practical (Hours per week)	Tutori al (Hours per week)	Credit	Continuous Assessment (CA) (Marks - 25)	Semester End Examinations (SEE) (Marks- 75 in Question Paper)
4	4		4+2	25	75

Learning Objectives:

1. To provide basic knowledge on intellectual property rights and their implications in biological research and product development;
2. To become familiar with India's IPR Policy;
3. To learn biosafety and risk assessment of products derived from biotechnology and regulation of such products;
4. To become familiar with ethical issues in biological research. This course will focus on consequences of biomedical research technologies such as cloning of whole organisms, genetic modifications, DNA testing

Course Outcomes:

After completion of the course, learners would be able to:

CO1: Understand the rationale for and against IPR and especially patents;

CO2: Understand why India has adopted an IPR Policy and be familiar with broad outline of patent regulations;

CO3: Understand different types of intellectual property rights in general and protection of products derived from biotechnology research and issues related to application and obtaining patents;

CO4 : Gain knowledge of biosafety and risk assessment of products derived from recombinant DNA research and environmental release of genetically modified organisms, national and international regulations;

CO5 : Understand ethical aspects related to biological, biomedical, health care and biotechnology research

Outline of Syllabus: (per session plan)

Module	Description	No of Hours
1	Introduction to IPR	15
2	Patenting	15
3	Biotech Research-and Regulations	15
4	Bioethics	15
	Total	60
PRACTICALS		

PRACTICAL I

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1. IPR based case studies- presentation
2. Patent filing- project

Unit	Topic	No. of Hours/Credits
Module 1	<p>Intellectual property : Introduction ; types of IP: patents, trademarks, copyright & related rights, industrial design, traditional knowledge, geographical indications, protection of new GMOs; International framework for the protection of IP; IP as a factor in R&D; IPs of relevance to biotechnology and few case studies.</p> <p>Introduction to history of GATT, WTO, WIPO and TRIPS; Protection of geographical indications: objectives, justification, international position, multi lateral treaties, national level, Indian position</p> <p>Protection of traditional knowledge: objective, concept of traditional knowledge, holders, issue concerning, bioprospecting and bio-piracy, alternative ways, protectability, need for a Suigeneris regime, traditional knowledge digital library</p> <p>Case study related to basamati rice & erythropoietin by Genetech . ; concept of ‘prior art’: invention in context of “prior art”; patent databases - country-wise patent searches (USPTO, EPO, India); analysis and report formation.</p> <p>Geographic indications- case studies</p>	15
Module 2	<p>Basics of patents: types of patents; Indian Patent Act 1970; recent amendments; WIPO Treaties; Budapest Treaty; Patent Cooperation Treaty (PCT) and implications; procedure for filing a PCT application; role of a Country Patent Office; filing of a patent application; precautions before patenting- disclosure/non-disclosure - patent application- forms and guidelines</p> <p>National Bio-diversity Authority (NBA) and other regulatory bodies, fee structure, time frames; types of patent applications: provisional and complete specifications;</p> <p>PCT and conventional patent applications; International patenting-requirement, procedures and costs; financial assistance for patenting introduction to existing schemes; publication of patents-gazette of India, status in Europe and US; patent infringement- meaning, scope, litigation, case studies and examples; commercialization of patented innovations; licensing – outright sale, licensing, royalty;</p> <p>Patenting by research students and scientists- university/organizational rules in India and abroad, collaborative research - backward and forward IP; benefit/credit sharing among parties/community, commercial (financial) and non-commercial incentives.</p>	15

Module 3	<p>Biosafety and Biosecurity - Primary containment for biohazards; biosafety levels; GRAS organisms, definition of GMOs & LMO concepts of familiarity and substantial equivalence; risk – environmental risk assessment and food and feed safety assessment; problem formulation – protection goals, compilation of relevant information, risk characterization and development of analysis plan</p> <p>International regulations – Cartagena protocol, OECD consensus documents and Codex Alimentarius; Indian regulations – EPA act and rules, guidance documents, regulatory framework – RCGM, GEAC, IBSC and other regulatory bodies;(repeat)</p> <p>Draft bill of Biotechnology Regulatory authority of India containments – biosafety levels and category of rDNA experiments; field trails – biosafety research trials – standard operating procedures - guidelines of state governments; GM labeling – Food Safety and Standards Authority of India (FSSAI).</p>	15
Module 4	<p>Ethical conflicts in biological sciences - interference with nature, bioethics in health care - patient confidentiality, informed consent, Euthanasia, artificial reproductive technologies, prenatal diagnosis, genetic screening, gene therapy, transplantation.</p> <p>Bioethics in research – cloning and stem cell research, Human and animal experimentation, animal rights/welfare, Agricultural biotechnology - Genetically engineered food, environmental risk, labeling and public opinion.</p> <p>Sharing benefits and protecting future generations - Protection of environment and biodiversity – biopiracy Environmental laws: acts concerning land, water and air. History of amendments. Pollution boards and their role, Social movements. Role of NGOs. World scenario</p>	15

Suggested Readings

1. Ganguli, P. (2001). Intellectual Property Rights: Unleashing the Knowledge Economy. New Delhi: Tata McGraw-Hill Pub.
2. National IPR Policy, Department of Industrial Policy & Promotion, Ministry of Commerce, GoI.
3. Complete Reference to Intellectual Property Rights Laws. (2007). Snow White Publication Oct.
4. Kuhse, H. (2010). Bioethics: an Anthology. Malden, MA: Blackwell.
5. Office of the Controller General of Patents, Design & Trademarks; Department of Industrial Policy & Promotion; Ministry of Commerce & Industry; Government of India. <http://www.ipindia.nic.in/>
6. Karen F. Greif and Jon F. Merz, Current Controversies in the Biological Sciences -Case Studies of Policy Challenges from New Technologies, MIT Press
7. David Pressman (2016) Patent It Yourself 18th edition, Nolo Publishers

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8. Ganguli, Prabuddha: Intellectual property rights : unleashing the knowledge economy. New Delhi. Tata Mcgraw-Hill Publishing Company Limited, 2001.
9. Sudeep Chaudhuri (2005), the WTO and India's Pharmaceutical industry, Oxford University Press.
10. Vandana Shiva (2002), Protect or Plunder? Understanding Intellectual Property Rights, Zed Books
11. Alexandra George (2006) Globalisation and Intellectual Property, Ashgate publishing company
12. Maarten Bode, (2008) Taking traditional knowledge to the market, Orient Longman Publishers

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