Course Code	Course Name	L-T-P	Credits	Year of Introduction
BT402	Bioprocess Plant Design and Safety	3-0-0	3	2016

Prerequisite : Nil

Course objectives

- To introduce the design of process plant equipment such as heat exchangers, absorbers, distillation column and bioreactors.
- To exposed the safety aspects of process plant.

Syllabus

General design considerations for a process plant, development of process flow sheets, P&I diagrams, planning and scheduling, plant layout, common materials of construction and their mechanical properties, design of heat transfer equipment, design of absorption column, design of distillation column, design of bioreactor, safety aspects.

Expected outcome

A student who successfully completes this course will be able to

i. Develop a process flow sheet.

ii. Understand P&I diagrams.

iii. Design heat exchangers

iv. Design absorption columns

v. Design distillation columns

vi. Explain the necessity for safety and safety guidelines.

References

1. Green, D.W., Perry, R.H., *Perry's Chemical Engineers' Handbook*, 8th Ed., McGraw-Hill, 2008.
2. J. M. Coulson, J. F. Richardson, R. K. Sinott, *Coulson and Richardson's Chemical Engineering Design*, Volume 6, Butterworth-Heinemann, 1999.
3. Peters, M. S., Timmerhaus, K. D., West, R. E., *Plant Design and Economics for Chemical Engineers*, 5/e, McGraw-Hill, 2003
4. V.V. Mahajani, S.B.Umarji, *Joshi's Process Equipment Design*, 4/e, Macmillan Publishers India Ltd., 2009.
5. B.C. Bhattacharya, *Introduction to Chemical Equipment Design: Mechanical Aspects*, CBS Publishers & Distributors, 2008.
6. Ray Sinnott, Gavin Towler, *Chemical Engineering Design*, Elsevier Limited, 2009.
7. Rajiv Dutta, *Fundamentals of Biochemical Engineering*, Springer Berlin Heidelberg, 2008.
8. D Q Kern, *Process Heat Transfer*, Tata McGraw-Hill Education, 1997.
9. BIS IS 2825:1969 (R2002) Code For Unfired Pressure Vessels.

Course plan			
Module	**Contents**	**Hours**	**Sem. Exam Marks**
I	General design considerations for a process plant, optimum design, development of process flow sheets, input-output structure (Hierarchy of decisions for Input-Output structure, overall material and energy balances, stream costs, process alternatives), Piping and Instrumentation (P&I) diagrams. Planning and scheduling. Utility supply aspects, Plant layout, Common materials of construction and their mechanical properties.	5	15%
II	Safety aspects of process plant-Good manufacturing practices; Necessity for safety, safety guidelines, common industrial accidents-causes and preventive measures, safety measures, Risk Assessment & HAZOP Study, HAZAN, chemical hazards, fire hazard, fire prevention, flame arrester, explosions. Types of plant maintenance, preventive, predictive, online, scheduled, corrective/breakdown.	5	15%
FIRST INTERNAL EXAM			
III	Heat exchangers - double pipe and shell and tube types; different parts, different flow patterns, factors influencing the design; Evaporators, evaporator operation conditions and design concerns; use of Chemical Engineers' Handbook for the design of double pipe heat exchangers, Shell and Tube Heat exchangers, Condensers and Evaporators	7	15%
IV	Design of bioreactors (Design Approach Only)- stirred tank fermenter, Fermenter parts and design, Design considerations for maintaining sterility of process streams and process equipments. Mechanical design aspect of pressure vessel (subjected to internal pressure only) using BIS IS 2825:1969 (R2002) Code For Unfired Pressure Vessels.	8	15%
SECOND INTERNAL EXAM			
V	Design of absorption columns-general features of tray and packed columns; capacity, flooding, entrainment, pressure drop; influencing factors; efficiency of contacting columns; Design of tray and packed absorption columns for a given internal material balance using Chemical Engineers' Handbook.	8	20%
VI	Design of distillation column- Design of distillation columns: Sieve plate, bubble cap distillation columns, Design variables in distillation, design methods for binary systems, plate efficiency, Design of tray columns for a given internal material balance using Chemical Engineers' Handbook- Design of plate, Down comers, Weir height, Gas velocity from nozzle, tray hydraulics of sieve, bubble cap trays, Plate efficiency, No of plates, approximate column sizing, plate hydraulic design.	9	20%
END SEMESTER EXAMINATION			

QUESTION PAPER PATTERN:

Maximum Marks: 100 Exam Duration: 3 hours

The question paper consists of Part A, Part B and Part C.

Part A consists of three questions of 15 marks each from Modules I and II. The student has to answer two question (15×2=30 marks).

Part B consists of three questions of 15 marks each from Modules III and IV. The student has to answer two question (15×2=30 marks).

Part C consists of three questions of 20 marks each from Modules V and VI. The student has to answer two question (20×2=40 marks).

For each question can have up to a maximum of 4 subparts.

Note: The students may be permitted to use Perry's Chemical Engineers' Hand Book, or similar data sources or attested copies of relevant pages of Perry's Chemical Engineers' Hand Book (any edition), IS Codes, Steam Tables and attested copies of relevant charts, data tables and empirical correlations in the examination.

Course Code	Course Name	L-T-P	Credits	Year of Introduction
BT404	Bioprocess Quality Control	3-0-0	3	2016

Prerequisite : Nil

Course objectives

- To introduce students to the quality control aspects of food and pharmaceutical industries.
- To understand various analytical methods to support process validation, quality control, quality standards and acts.

Syllabus

General consideration in quality of food and pharmaceuticals, Quality assurance and Quality management, general principles of bioprocess validation, analytical techniques used in process validation, sterilisation control, biosafety.

Expected outcomes

A student who successfully completes this course should be able to

i. Explain general considerations in quality of bioproducts.
ii. Explain quality assurance and quality management.
iii. Explain the working principle and application of instruments used in process validation.
iv. Explain the food laws and regulations in India
v. Explain the need for biosafety and safe practices.

Text Books

1. Hans-Jurgen Bassler, Frank Lehmann, *Containment Technology: Progress in the Pharmaceutical and Food Processing Industry*, Springer, 2013.
2. World Health Organization (WHO), *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines*, Volume 2.
3. Anurag S Rathore, Rohin Mhatre (Eds), *Quality by Design for Biopharmaceuticals: Principles and Case Studies*, Wiley, 2009.
4. Diane O Fleming, Debra A Long, *Biological Safety: Principles and Practices*, ASM Press, 4/e, 2006.
5. *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines*, Volume 2, World Health Organization.

Course Plan

Module	Contents	Hours	Sem. Exam Marks
I	Need for quality control in food and pharmaceutical industries, general considerations in quality of bioproducts (e.g. enzymes, antibiotics, pharmaceuticals, recombinant products) such as molecular identity, potency, purity and stability, toxicity, immunogenecity and consistency. Brief introduction to IP, BP and USP, quality attributes.	6	15%
II	Basic concepts of quality assurance: Quality assurance and Quality management in pharmaceutical industry. Requirements of GMP, cGMP, GLP, ISO 9000 series, Quality audits. Brief introduction to general requirements of health regulatory bodies such as US FDA, WHO. Statistical quality control, categories, quality control charts, Six Sigma quality control program, quality by design for biotech products.	8	15%

	FIRST INTERNAL EXAMINATION		
III	Bioprocess Validation: General principles and practices, Analytical methods to support process validation-Principle and applications of UV spectrophotometer, IR, FTIR, NMR, C-13 NMR, Mass spectra, Fluorescence and Atomic spectroscopy, Liquid scintillation spectrometry, Auto radiography, HPLC, HPTLC, gel chromatography, electrophoresis and ion-pair chromatography, GC-Mass, light, phase contrast, scanning and transmission electron microscopy, cytometry and flow cytometry. Thermogravimetry, Differential scanning calorimetry (DSC).	7	15%
IV	Sterilization control and sterility testing: batch and continuous heat sterilization, ultra high-temperature (UHT) processes, D value, z value, survival curve, Radiation, gaseous and filter sterilization, Chemical and biological indicators, Chemical disinfectants, clean-in-place (CIP) and sterilize-in-place (SIP) procedures, aseptic procedures necessary to achieve a sterile fermentation process.	7	15%
	SECOND INTERNAL EXAMINATION		
V	Quality standards-Salient features of Indian Food Safety regulations and acts, Food Laws and Regulations in India, Food Safety and Standards Act, 2006, Objectives, requirements and benefits of food grades and standards (BIS, AGMARK, PFA, FPO, CAC (Codex Alimantarious Commission), General Hygiene and Sanitation in food industry, Role of the FSSAI (The Food Safety and Standards Authority of India) in food safety.	6	20%
VI	Introduction to Biosafety, Need for biosafety, Basic methods for safe handling, transport, and storage of biological materials. Introduction to Biological safety cabinets-Horizontal & Vertical Laminar Air Flow Cabinet, Fume hood, Primary and secondary containments; Containment levels, Biosafety levels of specific Microorganisms (food and water borne pathogens), Infectious Agents (Chemicals and carcinogens). MSDS-Material Safety Data Sheet Understanding. Biosafety policy in India.	8	20%
	END SEMESTER EXAMINATION		

QUESTION PAPER PATTERN:

Maximum Marks: 100 Exam Duration: 3 hours

The question paper consists of Part A, Part B and Part C.

Part A consists of three questions of 15 marks each uniformly covering Modules I and II. The student has to answer two questions (15×2=30 marks).

Part B consists of three questions of 15 marks each uniformly covering Modules III and IV. The student has to answer two questions (15×2=30 marks).

Part C consists of three questions of 20 marks each uniformly covering Modules V and VI. The student has to answer two questions (20×2=40 marks).

For each question there can be a maximum of 4 subparts.

Course Code	Course Name	L-T-P	Credits	Year of Introduction
BT462	Biomaterials Engineering	3-0-0	3	2016

Prerequisite : Nil

Course objectives

- To provide information on common biomaterials and their basic properties, methods of characterisation of biomaterials, structure-function relationships, design of materials for biomedical applications and processing methods.

Syllabus

Common biomaterials and their unique properties, applications, methods of characterisation, structure-function relationships and biocompatibility, process to improve biocompatibility, design of materials for biomedical applications and processing methods, failure mechanisms.

Course outcomes

Upon successful completion of this course, the student will be able to

i. Explain different classes of biomaterials and their applications.
ii. Describe the fundamental properties of synthetic and natural biopolymers.
iii. Explain the characterisation techniques measure and the underlying scientific principles.
iv. Understand the structure-function relationship of biomaterials.
v. Describe the basic processing methods for biomaterials and failure mechanisms.

References

1. B D Ratner, A S Hoffman, F J Schoen, J E Lemons (Eds), *Biomaterials Science: An Introduction to Materials in Medicine*, Elsevier Academic Press, 2004.
2. William D Callister, *Materials Science and Engineering: An Introduction*, John Wiley and Sons, 2013.
3. Amit Bandyopadhyay, Susmita Bose, *Characterization of Biomaterials*, Elsevier, 2013.
4. C M Agarwal, J L Ong, Mark R Appleford, Gopinath Mani, *Biomaterials-Basic Theory with Engineering Applications*, Cambridge University Press, 2014.
5. Joon Park, R. S. Lakes, *Biomaterials an Introduction*, Springer, 2007.
6. Temenoff, Mikos, *Biomaterials-The Intersection of Biology and Materials Science*, Pearson Prentice Hall, 2008.

Course Plan

Module	Contents	Hours	Sem. Exam Marks
I	Introduction to biomaterials – definition of biomaterials, functions of biomaterials, common biomaterials and their applications-ceramics, chitosan, alginate, hydrogels, hyaluronan, polymers, composites, metals, important biometallic alloys: Ti-based, stainless steels, Co-Cr-Mo alloys, bioresorbable and bioerodable materials, biodegradable polymers, soft and hard tissue replacement, biotextiles, applications of common biomaterials.	6	15%
II	Basic properties of biomaterials -mechanical (elasticity, yield stress, ductility, toughness, strength, fatigue, hardness, wear resistance), tribological (friction, wear, lubricity), morphology and texture, physical (electrical, optical, magnetic, thermal), chemical and biological properties, surface properties.	7	15%

FIRST INTERNAL EXAM			
III	Characterisation of biomaterials –need for characterisation, techniques for microstructural characterisation, mechanical characterisation, surface characterisation, biological characterisation, what these techniques measure and the underlying scientific principles on which they are based, techniques to evaluate cell-biomaterial and bacteria-biomaterial interactions.	6	15%
IV	Structure-function relationships of natural biomaterials, concept of biocompatibility and sterility, assessment of biocompatibility, Phenomena at the biointerfaces, molecular and cellular processes with living environment, blood-materials interaction, short and long term reactions to the body, cell-material interactions and foreign body response, biomaterial-tissue interactions - biologic response, tissue compatibility testing, blood - materials interactions, .	8	15%
SECOND INTERNAL EXAM			
V	Design of materials for biomedical applications - cardiovascular, dental implants, orthopedic application, skin, ophthalmologic applications, wound healing, sutures, biomedical and biosensors, implantation techniques for soft tissue and hard tissue replacements, Standards on the biological evaluation of medical devices and implications to applications in human -ISO 10993.	8	20%
VI	Basic processing methods for biomaterials, as implants and medical devices, processing to improve bulk properties, processing to form desired shapes, processing of metals and ceramics, processing of polymers, processing to improve biocompatibility, failure mechanisms -stress corrosion, fracture, wear.	7	20%
END SEMESTER EXAMINATION			

QUESTION PAPER PATTERN:

Maximum Marks: 100 Exam Duration: 3 hours

The question paper consists of Part A, Part B and Part C.

Part A consists of three questions of 15 marks each from Modules I and II. The student has to answer two question (15×2=30 marks).

Part B consists of three questions of 15 marks each from Modules III and IV. The student has to answer two question (15×2=30 marks).

Part C consists of three questions of 20 marks each from Modules V and VI. The student has to answer two question (20×2=40 marks).

For each question there can be a maximum of 4 subparts.

Course Code	Course Name	L-T-P	Credits	Year of Introduction
BT464	Food Process Technology	3-0-0	3	2016

Prerequisite: Nil

Course objectives

- To familiarise the principles of food processing, various equipment used in food processing, properties of food, food spoilage and ways to enhance the shelf life of foods.
- To make aware the emerging technologies for food processing.

Syllabus

Properties of foods, Unit operations food processing, Common equipments used for processing foods, Food spoilage and methods to enhance shelf life, Emerging technologies for food processing.

Course outcomes

Upon successful completion of this course, the student should be able to

i. Explain properties of food in relation to its quality.
ii. Elucidate the theory and applications of unit operations in food processing.
iii. Describe the various equipments used in food industry.
iv. Explain the factors affecting the growth and survival of food microorganisms.
v. Describe various food preservation techniques.

References

1. P J Fellows, *Food Processing Technology: Principles and Practice*, 3/e, CRC Press, 2009.
2. B Sivasankar, *Food Processing and Preservation*, PHI Learning Pvt. Ltd., 2009.
3. Rao D G, *Fundamentals of Food Engineering*, PHI Learning Private Ltd., 2010.
4. R Paul Singh, Dennis R Heldman, *Introduction to Food Engineering*, 4/e, Elsevier, 2009.
5. Da-Wen Sun, *Emerging Technologies for Food Processing*, Elsevier, 2014.
6. PG Smith, *Introduction to Food Process Engineering*, 2/e, Springer, 2011.

Course plan

Module	Contents	Hours	Sem. Exam Marks
I	Properties of foods-size, shape, volume and related physical attributes, Rheological properties, Thermal properties, Electromagnetic properties, Biochemical properties, Sensory characteristics, main components in food, Nutritional quality. Measurement of colour, flavour, consistency, viscosity, texture and their relationship with food quality and composition.	6	15%
II	Unit operations in food processing - Fluid flow theory and applications, Heat transfer theory and applications, Drying, Evaporation, Contact equilibrium separation processes: theory and applications, Mechanical separations-Size reduction and classification. Mixing.	6	15%
	FIRST INTERNAL EXAM		
III	Equipments used in food processing (Theory and applications): pasteurizer, homogenizer, evaporators and concentrators, different types of freezers including plate freezers, blast freezer, cryogenic freezer, vacuum freezer.	8	15%

	Equipment used for grading and sizing of food, various types of driers, including trays drier, spray drier, fluidized bed drier, freeze drier, solar drier. Extraction, filtration, and centrifugation equipment. Extruder, Emulsifiers, crystallisation.		
IV	Food spoilage, microorganisms causing foods spoilage, factors affecting the growth and survival of microorganisms in food, chemical changes of foods caused by microorganisms, shelf life, determination of the presence of microorganisms and / or their products in Foods by various techniques.	6	15%
SECOND INTERNAL EXAM			
V	Food preservation processes-Water Activity and Food Preservation, Food preservation techniques using heat-Pasteurization and Blanching, Continuous flow sterilisation, Principles and process description of UHT processing. Principle of low temperature preservation, Freezing, Thawing. Heating, High-Pressure Processing, Food Irradiation.	8	20%
VI	Emerging technologies for food processing-principle and applications of High pressure processing, Pulsed electric field processing, Infrared heating, Non-thermal processing by radio frequency electric fields, Osmotic dehydration, Application of ultrasound and irradiation, Ohmic heating, Microwave heating, vacuum cooling, High pressure freezing. Use of antifreeze proteins in food preservation, Membrane processes in food processing.	8	20%
END SEMESTER EXAMINATION			

QUESTION PAPER PATTERN:

Maximum Marks: 100 Exam Duration: 3 hours

The question paper consists of Part A, Part B and Part C.

Part A consists of three questions of 15 marks each uniformly covering Modules I and II. The student has to answer two questions (15×2=30 marks).

Part B consists of three questions of 15 marks each uniformly covering Modules III and IV. The student has to answer two questions (15×2=30 marks).

Part C consists of three questions of 20 marks each uniformly covering Modules V and VI. The student has to answer two questions (20×2=40 marks).

For each question there can be a maximum of 4 subparts.

Course Code	Course Name	L-T-P	Credits	Year of Introduction
BT466	Nano biotechnology	3-0-0	3	2016

Prerequisite : Nil

Course objectives

- To understand the basics of Nano biotechnology and its applications.

Syllabus

Timelines and progress, prospects and challenges, applications of Nano biotechnology, basic principles underlying the fabrication of Nano scale structures and materials, characterisation of Nano materials, toxicity of Nano materials, Protein-based nanostructures, Lab-on-a-chip devices, biosensors, Microbial nanoparticles, ethical and societal issues in Nano biotechnology, life-cycle assessment and risk assessment of Nano materials.

Expected outcomes

Upon successful completion of this course, the student will be able to

i. Explain the applications of various types of Nano materials in biotechnology.
ii. Understand production and the applications of various types of nanostructured materials.
iii. Explain protein-based nanostructures protein-based nanostructures.
iv. Explain the basic principle and components of a biosensor.
v. Know methods of producing microbial nanoparticle and its applications.
vi. Describe ethical and socioeconomic challenges.

References

- Christof M Niemeyer, Chad A Mirkin (Eds.), *Nano biotechnology: Concepts, Applications and Perspectives*, Wiley VCH, 2004.
- Tuan Vo-Dinh (Ed.), *Nanotechnology in Biology and Medicine: Methods, Devices, and Applications*, CRC Press, 2007.
- Chandran Karunakaran, Kalpana Bhargava, Robson Benjamin (Eds.), *Biosensors and Bioelectronics*, Elsevier, 2015.
- David S Goodsell, *Bionanotechnology*, John Wiley & Sons, 2004.
- Mark Wiesner, Jean-Yves Bottero, *Environmental Nanotechnology: Applications and Impacts of nanomaterials*, McGraw Hill, 2007.

Course Plan

Module	Contents	Hours	Sem. Exam Marks
I	Nano biotechnology-introduction, development of Nano biotechnology - timelines and progress, prospects and challenges, applications - medical and diagnostics, environment, food, bioseparation, drug discovery and delivery, nanotechnology for tissue engineering: applications in regenerative therapy, analytical applications.	6	15%
II	Nano scale structures and materials (nanoparticles, nanowires, Nano fibers, nanotubes, Nano rods, Nano cages, Nano shells, quantum dots), basic principles underlying the fabrication of these Nano materials, interaction between biomolecules and nanoparticle surfaces, brief introduction to	8	15%

	structure and chemical characterisation of Nano materials, toxicity of Nano materials –biological toxicity and environmental toxicity, reasons for toxicity, toxicity assessment, modification of nanomaterials to make them ecofriendly.		
FIRST INTERNAL EXAM			
III	Protein-based nanostructures, Nano motors -bacterial (*E.coli*) and mammalian(Myosin family), nanoparticles in biological labeling and cellular imaging, science of nanoparticles functionalization, Nano printing of DNA, RNA, and proteins, Biochips applications in Nano scale detection, Lab-on-a-chip devices.	7	15%
IV	Biosensors-basic principle, components of a biosensor, classification of biosensors based on bioreceptors and transducers, molecular recognition, types of molecular recognition, molecular recognition elements, aptamers, applications of molecular recognition elements in nanosensing of different analytes, enzymatic biosensors, immunosensors.	7	15%
SECOND INTERNAL EXAM			
V	Microbial nanoparticles, biosynthesis of nanoparticles by microorganisms, methods of microbial nanoparticle production, applications of microbial nanoparticles, bacteriorhodopsin and its potential in technical applications-overview, structure, photoelectric applications, photochromic applications and applications in energy.	7	20%
VI	Ethical and societal issues in Nano biotechnology, socioeconomic challenges, ethical issues with special reference to Nano medicine, legal issues, life-cycle assessment and risk assessment of Nano materials.	6	20%
END SEMESTER EXAMINATION			

QUESTION PAPER PATTERN:

Maximum Marks: 100 Exam Duration: 3 hours

The question paper consists of Part A, Part B and Part C.

Part A consists of three questions of 15 marks each uniformly covering Modules I and II. The student has to answer two questions (15×2=30 marks).

Part B consists of three questions of 15 marks each uniformly covering Modules III and IV. The student has to answer two questions (15×2=30 marks).

Part C consists of three questions of 20 marks each uniformly covering Modules V and VI. The student has to answer two questions (20×2=40 marks).

For each question there can be a maximum of 4 subparts.

Course Code	Course Name	L-T-P-	Credits	Year of Introduction
BT468	**Entrepreneurship, IPR and Biosafety**	**3-0-0**	**3**	**2016**

Prerequisite : Nil

Course Objectives

- To introduce the fundamental aspects of Entrepreneurship, Intellectual property Rights and Patents
- To prepare the students to consider Entrepreneurship as a career option.
- To impart knowledge about the concepts and importance of Biosafety in a modern biotechnology industry.

Syllabus

Rapid progress in Biotechnology and development of new products and services has introduced a host of critical issues relating Intellectual property Rights and Patents. This course provides a broad coverage of Entrepreneurship, IPR, Biosafety and Bioethics.

Expected outcome

Upon successful completion of this course, the student will be able to

i. Explain types of intellectual property and laws for protecting intellectual property.
ii. Explain patents and search patent data bases.
iii. Explain patenting procedures and able to file patents.
iv. Describe the traits of an entrepreneur and kinds of entrepreneurs.
v. Recognize biosafety issues and the importance of biosafety in the laboratory.

Reference Books

1. Deepa Goel and Shomini Parashar, *IPR, Biosafety and Bioethics*, Pearson Education, 2013.
2. R Radhakrishnan, S. Balasubramanian, *Intellectual Property Rights: Text and Cases*, Excel Books, New Delhi, 2008.
3. P Ganguli, *Gearing Up for Patents: The Indian Scenario*, Universities Press (India) Ltd., 1998.
4. R K Jain, *Patents: Procedures and Practices*, Universal Law Publishing, 2011.
5. M K Sateesh, *Bioethics and Biosafety*, I. K. International Publishing House, New Delhi, 2008.

Course Plan

Module	Contents	Hours	Sem. Exam Marks
I	Entrepreneurship: Definition, functions and kinds of entrepreneurs, intrapreneur-entrepreneurship and economic development, entrepreneurial competencies-traits, developing competencies, project identification, selection and financing. Project report-content and significance, Planning Commission's guidelines for formulating project reports-methods of project appraisals.	6	15%
II	Traits of an entrepreneur, tools for detecting entrepreneurial traits - Thematic Apperception Test (TAT), Inkblot test, case studies - successful entrepreneurs in India and abroad, Innovation - generating project ideas, interaction with research institutions, Technology-Business incubators, Project financing - financing schemes for different types of entrepreneurs, venture capital.	6	
FIRST INTERNAL EXAMINATION			

III	Introduction to intellectual property rights (IPR): Concepts of IPR, need for IPR, IPR in India - genesis and development, trademarks, trade secret, domain names, geographical indications, copyright and related rights, some important examples of IPR, traditional knowledge, protection of GMOs, IP as a factor in R&D; IPs of relevance to biotechnology agreements and treaties, GATT & TRIPS Agreement, Madrid Agreement, Hague Agreement, WIPO Treaties, Budapest Treaty, PCT; Indian Patent Act 1970 & recent amendments.	8	15%
IV	Patents: Classification of patents in India, classification by WIPO, special patents, patenting biological products, factors justifying patentability of biotechnological inventions, problems in biotechnology patenting, patentable ingredients of biotechnology, patent cooperation treaty (PCT), concept of prior-art, types of patent applications, patenting procedures, national and international patent databases and searching, United States Patent and Trademark Office (USPTO), European Patent Office (EPO), PatentScope (WIPO), Intellectual property office, India (IPO), national & PCT filing procedure, time frame and cost, status of the patent applications filed, precautions while patenting-disclosure/non-disclosure, financial assistance for patenting-introduction to existing schemes, patent licensing and agreement, patent infringement-meaning, scope, litigation, trade mark registration in India.	7	15%
SECOND INTERNAL EXAMINATION			
V	Introduction to biosafety: Overview of biosafety, risk groups and biosafety levels, process of risk assessment, Biosafety guidelines - Government of India; Definition of GMOs & LMOs; concerns and challenges of GMO, National and international regulatory bodies for dealing GMO in research and in commercial applications, environmental release of GMOs, Cartagena protocol on biosafety, salient features, different organisations and data base information on biosafety. GMOs – case studies of relevance in India.	8	20%
VI	Introduction to bioethics, different approaches to ethics, bioethical issues and conflicts in the development of GMOs, transgenic, gene therapy and human cloning, other major issues such as socioeconomic, sociolegal, environmental, and health and safety issues, Bioethics advisory committees, case studies in IPR and biosafety.	7	20%
END SEMESTER EXAMINATIONINATION			

QUESTION PAPER PATTERN:

Maximum Marks: 100 Exam Duration: 3 hours

The question paper consists of Part A, Part B and Part C.

Part A consists of three questions of 15 marks each uniformly covering Modules I and II. The student has to answer two questions (15×2=30 marks).

Part B consists of three questions of 15 marks each uniformly covering Modules III and IV. The student has to answer two questions (15×2=30 marks).

Part C consists of three questions of 20 marks each uniformly covering Modules V and VI. The student has to answer two questions (20×2=40 marks).

For each question there can be a maximum of 4 subparts.