

Code: 9A23801

B.Tech IV Year II Semester (R09) Regular Examinations, March/April 2013  
**BIOETHICS, BIOSAFETY & INTELLECTUAL PROPERTY RIGHTS**  
(Biotechnology)

Time: 3 hours

Max. Marks: 70

Answer any FIVE questions.  
All questions carry equal marks.

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- 1 What is bioethics? Explain its significance.
- 2 Justify the statement 'biosafety concerns are important and have to be addressed for biotechnology research'.
- 3 Explain the salient features of biosafety guidelines of India. Add a note on the role of IBC & GEAC.
- 4 What are the regulatory requirements for drugs and biologicals?
- 5 Explain the methodology of drafting and filing of patent application.
- 6 What are trademarks? How do companies and organizations benefit from trademark protection?
- 7 Explain the role of various conventions for IP protection in Biotechnology.
- 8 Explain TRIPS agreement. Add a note on its implications.

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- 1 What are stem cells? Explain the ethical issues associated with stem cells.
- 2 Define biosafety. Add a note on its implications.
- 3 List out and briefly explain various biosafety committees as per the biosafety guidelines of India.
- 4 Write a brief account of the following:  
(a) GLP (b) GMP.
- 5 Explain the types of IPR's with suitable examples.
- 6 What are trade secrets? Compare it with other IP forms.
- 7 Write an overview of the convention on biological diversity.
- 8 What is GATT? Explain its salient features.

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- 1 Briefly explain the ethical issues associated with the following  
(a) Transplantation (b) Cord blood cells.
- 2 What are biosafety levels? Explain BSL's for infectious agents and infected animals.
- 3 What are the special biosafety procedures to be adopted for rDNA based products?
- 4 Define the term regulatory affairs. Explain its role in pharmaceutical and Biotechnology sector.
- 5 What are patents? Explain the criteria for patentability.
- 6 What are farmers and plant breeders rights? How do they protection these rights and benefit from it?
- 7 Briefly explain the following:  
(a) UPOV (b) PCT.
- 8 What is the role of TRIPS in creation and protection of Biotechnology IP?

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- 1 Discuss various social and ethical issues in Biotechnology.
- 2 Explain the biosafety issues concerning human health and environment.
- 3 What are the biosafety implications of using genetically modified organisms and their release into the environment?
- 4 Write an overview of guidelines of the following agencies for Biotechnology sector.  
(a) USFDA (b) EMEA.
- 5 What are intellectual property rights? What is the significance of protecting IP?
- 6 Define copyright. Explain its significance with suitable examples.
- 7 What is WIPO? Explain its role with reference to Biotechnology.
- 8 Discuss the role and responsibilities of WTO.

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