

**Gandhi Institute of Engineering and Technology University, Odisha, Gunupur
(GIET University)**



B. Tech (Eighth Semester - Regular) Examinations, April - 2025

21BBTPE48011 - IPR, Bioethics and Biosafety

(BIOTECHNOLOGY)

Time: 3 hrs

Maximum: 70 Marks

**Answer ALL questions
(The figures in the right hand margin indicate marks)**

PART – A

(2 x 5 = 10 Marks)

Q.1. Answer **ALL** questions

- | | CO # | Blooms
Level |
|--|------|-----------------|
| a. Why is it essential to protect Intellectual Property? | CO1 | K2 |
| b. Give one example each of a geographical indication and a traditional knowledge-based product. | CO1 | K1 |
| c. What is the objective of the Budapest Treaty? | CO2 | K1 |
| d. Name the recommended biosafety level for handling <i>Mycobacterium tuberculosis</i> . | CO3 | K2 |
| e. Write the principles of bioethics? | CO4 | K2 |

PART – B

(15 x 4 = 60 Marks)

Answer **all** the questions

- | | Marks | CO # | Blooms
Level |
|--|-------|------|-----------------|
| 2. a. Analyze the evolution of international IP protection by discussing the role of GATT, WTO, WIPO and TRIPS. | 15 | CO1 | K3 |
| (OR) | | | |
| b. Compare process patent and product patent using suitable examples from the pharmaceutical or agricultural sector. | 8 | CO1 | K4 |
| c. Discuss various types of intellectual property rights. | 7 | CO1 | K4 |
| 3.a. What is patentability requirement? Discuss the procedure of patent filing in India. | 5+10 | CO2 | K5 |
| (OR) | | | |
| b. Describe the international patenting procedure under the PCT system. Why is it beneficial for inventors? | 8 | CO2 | K5 |
| c. Illustrate the importance of conducting a prior art search before filing a patent. | 7 | CO2 | K4 |
| 4.a. Explain in detail the four Biosafety Levels (BSL-1 to BSL-4) and match them with appropriate organisms and containment protocols. | 15 | CO3 | K4 |
| (OR) | | | |
| b. Evaluate the functions of IBSC and RCGM in overseeing institutional biosafety in GMO research. | 8 | CO3 | K4 |
| c. Analyse how the role of GEAC in deployment of GMOs in Indian agriculture. | 7 | CO3 | K4 |
| 5.a. Analyse the international and national regulatory frameworks governing transgenics and human genome research, including the Cartagena Protocol. | 15 | CO4 | K4 |
| (OR) | | | |
| b. How would the principles of Good Clinical Practice (GCP) apply in a vaccine trial? | 8 | CO4 | K2 |
| c. Discuss the role of ELSI in guiding ethical human genome research and policy formation. | 7 | CO4 | K4 |

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