



B.E/B.TECH DEGREE EXAMINATIONS: NOV/DEC 2023

(Regulation 2018)

Seventh Semester

BIOTECHNOLOGY

U18BTE0011: Industrial Biosafety and Bioethics

COURSE OUTCOMES

CO1: Describe various risk assessments and associated biosafety practices at industrial level.

CO2: Demonstrate and classify biosafety levels.

CO3: Elucidate various biosafety guidelines, norms and regulations.

CO4: Assess GMO's and its regulation in terms of environmental release.

CO5: Acquire knowledge on ethical issues, guideline and regulations.

CO6: Discuss environmental release of GMOs and their impact.

Time: Three Hours

Maximum Marks: 100

Answer all the Questions:-

PART A (10 x 2 = 20 Marks)

(Answer not more than 40 words)

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| 1. Describe the classification of biohazards. | CO1 | [K ₂] |
| 2. Write the significance of PPE working with biohazards. | CO1 | [K ₂] |
| 3. Differentiate primary and secondary contaminants. | CO2 | [K ₃] |
| 4. Define MSDS? | CO2 | [K ₂] |
| 5. Discuss the different biosafety level. | CO3 | [K ₂] |
| 6. Summarize the specific role of FDA on industrial biosafety guidelines? | CO3 | [K ₁] |
| 7. List the precautions need to take after the environmental release of GMOs. | CO4 | [K ₃] |
| 8. Enlist the different methods to perform risk analysis of GMOs. | CO4 | [K ₂] |
| 9. List out challenges faced by the ethical committee on its performance. | CO5 | [K ₃] |
| 10. Enlist the functions of IBSC. | CO6 | [K ₂] |

Answer any FIVE Questions:-

PART B (5 x 16 = 80 Marks)

(Answer not more than 400 words)

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| 11. a) Differentiate types of accidents in manufacturing industry, list the first aid and precautionary measures. | 8 | CO1 | [K ₂] |
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	b)	What are the basic methods for safe handling, transport, and storage of biological and chemical materials?	8	CO1	[K ₁]
12.	a)	Distinguish the primary containment devices for biosafety level maintenance	6	CO2	[K ₃]
	b)	Classify the set of preventative measures designed to reduce the risk of transmission of infectious agents infected animals (test animals).	10	CO2	[K ₂]
13.	a)	Elaborate on the requirements for obtaining FPD mark and give examples of food products requiring FPD mark?	8	CO3	[K ₃]
	b)	How do biosafety and Biosecurity professional at FDA is involved in addressing the challenges posed by COVID-19.	8	CO3	[K ₄]
14.	a)	Describe the various risks associated with the use GMOS?	6	CO4	[K ₂]
	b)	Discuss all the essential information is required to conduct a comprehensive risk assessment of GMOS?	10	CO4	[K ₃]
15.		Which is the function of ethical committee of India?	16	CO5	[K ₂]
16.	a)	Explain concept of the advanced informed agreement (AIA) under the Cartagena protocol.	8	CO6	[K ₂]
	b)	Enumerate the role of IACUC, IBSC in regulating release of GMOs.	8	CO6	[K ₄]
