



Seat No. : \_\_\_\_\_

# NI-144

November-2025

M.Sc., Sem.-III

MIC-504 : Microbiology

(Concept of Bio-Business)

Time : 2:30 Hours]

[Max. Marks : 70

1. Which biotechnology background or skills are a must for Entrepreneurship in Bio business ? 14

**OR**

1. (A) Define and differentiate terms creation, invention, and innovation with an example. 7
1. (B) Why are bio-innovations important and the need of the hour ? 7

2. Write a detailed note on the different Intellectual Property Rights (IPR) types. 14

**OR**

2. (A) Describe the problem of patent trolls and explain how counterfeiting and piracy also pose challenges to IPR enforcement. 7
2. (B) Explain the importance of WIPO in patent law harmonization. 7

3. Describe basic principles and activities of Quality Control and Quality Assurance. 14

**OR**

3. (A) What is bioethics ? Write about the four principles of bioethics. 7
3. (B) Discuss the purpose, principle, and history of the Indian pharmacopoeia in detail. 7

4. Write an exhaustive note on Bioethics principles and codes. 14

**OR**

4. (A) Discuss the Risk groups and various biosafety levels assigned. 7
4. (B) Give a detailed note on the phases involved in a clinical trial. 7

5. Answer the following : (any **seven**)

**14**

- (1) What is a prototype ?
  - (2) What are frugal innovations ?
  - (3) Name a few startup schemes of the Government, central/state, for entrepreneurship development.
  - (4) Name any four products granted a Geographical Indication (GI) tag.
  - (5) State method/s adopted for IP valuation.
  - (6) What was the central legal question in the Diamond v. Chakrabarty case ?
  - (7) What is ISO 9001:2015 ?
  - (8) Why do we need regulatory agencies ?
  - (9) Define “Good Laboratory Practice”.
  - (10) What is a biosafety cabinet ?
  - (11) Give Full form : RCGM, GEAC.
  - (12) What are hits and leads in the context of drug discovery ?
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