

**GUJARAT NATIONAL LAW UNIVERSITY
GANDHINAGAR**

Course: **Law of Biotechnology and Challenges of Traditional Knowledge**
Semester- II (Batch: 2023-24)

End Semester Examination: April 2024 (LL M)

Date: 29th April, 2024

Duration: 3 hours

Max. Marks: 50

Instructions:

- Read the questions properly and write the answers in the given answer book.
- Do not write anything on the question paper.
- The respective marks for each question are indicated in-line.
- Indicate correct question numbers in front of the answer.
- No questions or clarification can be sought during the exam period, answer as it is, giving reason, if any.
- Word Limit: 12 Marks:1000 words, 7 Marks: 500-600 words.

	Marks
Q.1 Discuss the law relating to patenting biotechnology inventions and comparing the IPR regime in India, the USA and Europe.	(12)
Q.2 Discuss the trade and environmental-related issues due to living modified organisms and the legal regulations surrounding it.	(12)
Q.3 Discuss ethical and legal issues arising due to reproductive and therapeutic cloning and regulatory response.	(12)
Q.4 What encompasses gene therapy and gene therapy products according to the national guidelines for gene therapy product development and clinical trials 2019"? Discuss the ethical legal issues surrounding gene therapy.	(7)
Q.5 Discuss the various stages of clinical trials. Add a note on regulatory authority for conducting clinical trials in India and its role.	(7)
