

**GUJARAT NATIONAL LAW UNIVERSITY  
GANDHINAGAR**

**Course: Pharmaceutical Sciences (including Medical Devices)  
Semester- IV (Batch: 2020-25)**

**End Semester Online Examination: May 2022**

**Date: 15<sup>th</sup> May, 2022**

**Duration: 8 hours**

**Max. Marks: 40**

**Instructions:**

- 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.
- Diagram/s shall be made with a pencil only.
- Word Limit: 8 Marks: 650-700 words.

	<b>Marks</b>
Q.1 What are crude drugs? Describe in brief the steps involved in the cultivation, collection, and storage of crude drugs.	(8)
Q.2 What is biotransformation? Explain the Phase-I and Phase-II drug metabolism.	(8)
Q.3 Briefly discuss the minimum requirements of drug manufacturing units as per "Schedule M" under the Drugs and Cosmetics Act, 1940 and the rules thereunder?	(8)
Q.4 What are Biologics? How is it different from Similar Biologics? Explain the regulatory requirements that govern the marketing authorization of Similar Biologics in India.	(8)
Q.5 Briefly discuss the salient features of <i>The New drugs and Clinical trials rules 2019</i> .	(8)

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