GUJARAT NATIONAL LAW UNIVERSITY GANDHINAGAR Course: Pharmaceutical Sciences (including Medical Devices) Semester- IV (Batch: 2021-26)

End Semester Examination: May 2023

Date: 13th May, 2023 Duration: 2 hours Max. Marks: 40 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.
- Draw diagrams only with pencil.
- No questions or clarification can be sought during the exam period, answer as it is, giving reason, if any.
- Word Limit: 6 Marks: 250-300 words, 2 Marks: 50-60 words.

Part: A

- Q.1 Write short note on **any five** of the following:
 - a) Purple Book
 - b) Endocannabinoid System
 - c) Emergency Use Authorization
 - d) National list of Essential Medicine
 - e) Kieselguhr
 - f) Sutures

Part: B

(Answer **any five** of the following questions)

Q.2	Explain the key features of the Drug (Price Control) Order, 2013. How is the price of a new drug fixed under this order?	(6)
Q.3	Briefly discuss the key features of Medical Devices Rules, 2017.	(6)
Q.4	Explain the stages involved in the development of New Drugs.	(6)
Q.5	Explain with the help of a labeled diagram the various processes involved in the neurotransmitter action.	(6)
Q.6	Differentiate between biologics, biosimilars and generics with the help of examples.	(6)
Q.7	What are the roles and responsibilities of the Indian Pharmacopoeia Commission?	(6)

Marks

(2x5 =

10)