

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM – SEMESTER – VII EXAMINATION – WINTER-2025

Subject Code:BP702TT

Date:15-11-2025

Subject Name: Industrial Pharmacy II

Time: 10:30 AM TO 01:30 PM

Total Marks: 80

Instructions:

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- | | | |
|-------------|--|-----------|
| Q.1 | (a) Write a brief note on ISO 9000 series of quality standards. | 06 |
| | (b) What is CDSCO? Explain function of CDSCO in details. | 05 |
| | (c) Briefly discuss approval procedures for new drugs. | 05 |
| Q.2 | (a) Discuss on NABL certification in detail. | 06 |
| | (b) What is Investigational New Drug (IND) Application? Explain Requirement and types of an IND. | 05 |
| | (c) Write a note on Certificate of Pharmaceutical Product (COPP). | 05 |
| Q.3 | (a) Write on Quality Risk Management. | 06 |
| | (b) Write a note on Six sigma as a tool for quality management | 05 |
| | (c) Write a note on state licensing authority under Indian regulatory requirements. | 05 |
| Q.4 | (a) Discuss historical overview of regulatory affairs. | 06 |
| | (b) Write the protocol to conduct non clinical testing. | 05 |
| | (c) Explain benefits and key elements QbD. | 05 |
| Q.5 | (a) Write a note on “Approved regulatory bodies and agencies of India for TT” | 06 |
| | (b) Justify role of biostatistics in pharmaceutical product development | 05 |
| | (c) What is SUPAC? Give SUPAC guidelines for modified release dosages form. | 05 |
| Q. 6 | (a) Describe Pilot plant scale up considerations for solid dosage forms. | 06 |
| | (b) Discuss selection of pharmaceutical packaging materials. | 05 |
| | (c) What are the objectives and significance of pilot plants? | 05 |
| Q.7 | (a) Compare the following: a) Responsibilities of SU’s and RU’s b) Do’s and Don’ts of TT agreements. | 06 |
| | (b) Describe the procedure for new drug approval from CDSCO in India. | 05 |
| | (c) Write in brief about APCTD and NRDC. | 05 |
