

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER-7 EXAMINATION – WINTER -2023

Subject Code: BP702TT**Date: 04/12/2023****Subject Name: Industrial Pharmacy II****Time: 10.30 a.m. to 1.30 p.m.****Total Marks: 80****Instructions:**

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

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| Q.1 | (a) Define Pilot plant and scale up. Discuss importance of pilot plant study. | 06 |
| | (b) Explain in brief SUPAC guidelines for immediate release solid oral dosage forms. | 05 |
| | (c) Write a detail note on pilot plant scale up of tablets. | 05 |
| Q.2 | (a) Write a note on scope and organization management as per WHO guideline. | 06 |
| | (b) Describe documentation requirement for transfer the technology from R & D to manufacture level. | 05 |
| | (c) Briefly describe technology transfer protocol. | 05 |
| Q.3 | (a) What is Investigational New Drug (IND) Application? Explain Requirement and types of an IND. | 06 |
| | (b) Explain Clinical trial Management Studies in details. | 05 |
| | (c) Describe the role and responsibility of regulatory affairs professionals. | 05 |
| Q.4 | (a) Write a brief note on ISO 9000 series of quality standards | 06 |
| | (b) Explain purpose, benefits and elements Total Quality Management. | 05 |
| | (c) Discuss on NABL certification in detail. | 05 |
| Q.5 | (a) Write a note on Certificate of Pharmaceutical Product (COPP). | 06 |
| | (b) What is CDSCO? Explain function of CDSCO in details. | 05 |
| | (c) Explain Organization and Responsibilities of State Licensing Authority in India. | 05 |
| Q.6 | (a) Explain platform technology with respect to pilot plant scale up technique. | 06 |
| | (b) Describe the importance of Investigator's Brochure. | 05 |
| | (c) Explain review process for New Drug Application (NDA). | 05 |
| Q.7 | (a) Write a note on "Approved regulatory bodies and agencies of India for TT". | 06 |
| | (b) Write a note on Out of Specifications (OOS). | 05 |
| | (c) Briefly discuss approval procedures for new drugs. | 05 |
