

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.Ph -SEMESTER-VII • EXAMINATION – WINTER -2020**

**Subject Code: BP702TT****Date: 04/01/2021****Subject Name: INDUSTRIAL PHARMACY II****Time: 10:30AM To 12:30PM****Total Marks: 54****Instructions:**

1. Attempt any **THREE** questions from Q-1 to Q-6.
2. Q.7 is compulsory to attempt.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks.

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|------------|--|-----------|
| <b>Q.1</b> | (a) Describe the procedure for new drug approval from CDSCO in India.                                | <b>06</b> |
|            | (b) Describe the investigator's brochure for IND.  | <b>05</b> |
|            | (c) Write short note on Six sigma as a tool for quality management.                                  | <b>05</b> |
| <b>Q.2</b> | (a) Write the benefits of ISO to an organization. Write a note on ISO 9001:2008.                     | <b>06</b> |
|            | (b) Describe the basic concepts of TQM.  | <b>05</b> |
|            | (c) Discuss change control in quality management system.   | <b>05</b> |
| <b>Q.3</b> | (a) Explain in brief SUPAC guidelines for immediate release solid oral dosage forms.                 | <b>06</b> |
|            | (b) Write a note on platform technology citing appropriate example.                                  | <b>05</b> |
|            | (c) Write briefly on NABL certification.   | <b>05</b> |
| <b>Q.4</b> | (a) Write a detail note on pilot plant scale up of tablets.  | <b>06</b> |
|            | (b) Discuss selection of pharmaceutical packaging materials.   | <b>05</b> |
|            | (c) Explain the documentation in technology transfer.  | <b>05</b> |
| <b>Q.5</b> | (a) Write a note on "Approved regulatory bodies and agencies of India for TT".                       | <b>06</b> |
|            | (b) Write about role of regulatory affairs department.   | <b>05</b> |
|            | (c) Write a note on COPP.  | <b>05</b> |
| <b>Q.6</b> | (a) What is Technology transfer? Write importance of Technology transfer in pharmaceutical industry. | <b>06</b> |
|            | (b) Discuss in detail various factors affecting design of a pharmaceutical pilot plant facility.     | <b>05</b> |
|            | (c) Write a note on clinical research protocol.  | <b>05</b> |
| <b>Q.7</b> | (a) Write a brief note on qualification and validation in technology transfer.                       | <b>06</b> |
|            | <b>OR</b>  |           |
|            | (a) Write a note on state licensing authority under Indian regulatory requirements.                  | <b>06</b> |
|            | <b>OR</b>  |           |
|            | (a) Write the protocol to conduct non clinical testing.  | <b>06</b> |

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