

GUJARAT TECHNOLOGICAL UNIVERSITY**B.Ph. - SEMESTER- VII• EXAMINATION – SUMMER -2022****Subject Code: BP702TT****Date:03/06/2022****Subject Name: Industrial Pharmacy II****Time: 02:30PM TO 05:30PM****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) What is Six Sigma. Describe the importance of six sigma in achieving “zero defect”? **06**
(b) Describe in general out of specifications with respect to quality management? **05**
(c) Introduce ISO 9000 as a series of quality system standards. **05**
- Q.2** (a) Describe documentation required for changes in batch size as per SUPAC guidelines. **06**
(b) Discuss pilot plant scale up consideration for semi-solids. **05**
(c) Write a note on significance of space requirement for scale up techniques. **05**
- Q.3** (a) Discuss platform technology for scale up techniques with appropriate examples. **06**
(b) Describe importance of raw materials with respect to pilot plant scale up. **05**
(c) Write a note on certificate of pharmaceutical product (COPP). **05**
- Q.4** (a) Discuss the scope of WHO guidelines on transfer of technology in pharmaceutical manufacturing. **06**
(b) Write a detailed note on various level of changes in SUPAC guidelines. **05**
(c) Describe the organization and responsibilities of CDSCO. **05**
- Q.5** (a) Write a note on various agencies involved in technology transfer in India. **06**
(b) Discuss technology transfer related documentation for confidentiality agreement. **05**
(c) Briefly discuss approval procedures for new drugs in CDSCO. **05**
- Q. 6** (a) Introduce quality risk management with respect to technology transfer. **06**
(b) Explain the importance of Investigator’s Brochure. **05**
(c) Convey historical overview of Regulatory Affairs. **05**
- Q.7** (a) What is IND Application. Discuss Emergency use IND Application. **06**
(b) Briefly describe Management of Clinical trials. **05**
(c) Describe the responsibility of regulatory affairs professionals. **05**
