

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm - SEMESTER– VII• EXAMINATION – SUMMER -2021

Subject Code: BP702TT

Date: 04/08/2021

Subject Name: Industrial Pharmacy II

Time: 10:30AM TO 01:30PM

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) Write a detailed note on various level of changes in SUPAC guidelines. **06**
(b) Discuss pilot plant scale up consideration for oral liquids. **05**
(c) Discuss general consideration for space requirement for scale up techniques. **05**
- Q.2** (a) Discuss various documentation required for changes in batch size as per SUPAC guidelines. **06**
(b) Introduce platform technology with respect to pilot plant scale up technique. **05**
(c) What is Certificate of Pharmaceutical Product? **05**
- Q.3** (a) Discuss the scope of WHO guidelines on transfer of technology in pharmaceutical manufacturing. **06**
(b) Briefly describe technology transfer protocol. **05**
(c) Write a note on various technology transfer agencies in India. **05**
- Q.4** (a) Discuss confidentiality agreement in Technology Transfer. **06**
(b) Write in brief about Quality Risk Management with respect to Technology Transfer. **05**
(c) Describe in brief responsibilities of CDSCO. **05**
- Q.5** (a) What is IND Application. Discuss Emergency use IND Application. **06**
(b) Convey historical overview of Regulatory Affairs. **05**
(c) Briefly describe Management of Clinical trials. **05**
- Q. 6** (a) Describe the responsibility of regulatory affairs professionals. **06**
(b) Describe the importance of Investigator's Brochure. **05**
(c) Briefly discuss approval procedures for new drugs. **05**
- Q.7** (a) What is Six Sigma? Discuss the importance of Six Sigma concept. **06**
(b) Write a brief note on ISO 9000 series of quality standards **05**
(c) Write a note on procedure for change control. **05**
