

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. - SEMESTER - I • EXAMINATION -SUMMER • 2018

Subject Code: MQA104T**Date: 09-05-2018****Subject Name: PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER****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) Give format and content of IND in detail. **06**
(b) During product development how stability testing occurred? **05**
(c) Describe packaging materials and common testing method used for medical device packaging. **05**
- Q.2** (a) What is solubility? Describe methods of increasing solubility. **06**
(b) Discuss different steps involved in clinical research Process for Drug Discovery and Development. **05**
(c) What is Preformulation? What are objectives and principle of preformulation? **05**
- Q.3** (a) Which are the different opportunities and challenges of new era of drug product? **06**
(b) Briefly explain large scale manufacturing techniques of parenteral dosage form. **05**
(c) Write a Short note on BACPAC. **05**
- Q.4** (a) Discuss selection and evaluation of pharmaceutical packaging materials. **06**
(b) What are the difference between NDA and ANDA? **05**
(c) Discuss qualitative and quantitative models of technology transfer. **05**
- Q.5** (a) What is Technology Transfer? Discuss steps involved in technology transfer process. **06**
(b) Describe different types of pharmaceutical packaging materials. **05**
(c) What is Pilot Plant design? Give layout of pilot plant scale up. **05**
- Q.6** (a) Briefly explain Quality control test for container, closure and secondary packaging materials. **06**
(b) Explain Documentation in technology transfer. **05**
(c) Write a short note on Polymorphism. **05**
- Q.7** (a) Write a short note on SUPAC for non-sterile semisolid dosage form including creams. **06**
(b) What is an Aseptic packaging system? What are advantages and types of Aseptic packaging systems? **05**
(c) Describe optimization and production of technology transfer. **05**
