

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER-1 EXAMINATION – SUMMER-2019

Subject Code: MQA104T**Date: 04/06/2019****Subject Name: Product Development and Technology Transfer****Time: 02:30 PM TO 05:30 PM****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) | Explain product registration guidelines according to CDSCO | 06 |
| | (b) | Write a short note on Polymorphism. | 05 |
| | (c) | What is an Aseptic packaging system? What are advantages and types of Aseptic packaging systems? | 05 |
| Q.2 | (a) | What are the difference between NDA and ANDA? | 06 |
| | (b) | Explain Documentation in technology transfer. | 05 |
| | (c) | Which are the different opportunities and challenges of new era of drug product? | 05 |
| Q.3 | (a) | Write a short note on SUPAC for non-sterile semisolid dosage form including creams. | 06 |
| | (b) | During product development how stability testing occurred? | 05 |
| | (c) | What is Pilot Plant design? Give layout of pilot plant scale up. | 05 |
| Q.4 | (a) | Give format and content of IND in detail. | 06 |
| | (b) | Describe optimization and production of technology transfer. | 05 |
| | (c) | Describe packaging materials and common testing method used for medical device packaging. | 05 |
| Q.5 | (a) | Briefly explain Quality control test for container, closure and secondary packaging materials. | 06 |
| | (b) | What is solubility? Describe methods of increasing solubility. | 05 |
| | (c) | Briefly explain large scale manufacturing techniques of parenteral dosage form. | 05 |
| Q. 6 | (a) | What is Technology Transfer? Discuss steps involved in technology transfer process. | 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.7 | (a) | Discuss qualitative and quantitative models of technology transfer. | 06 |
| | (b) | Describe different types of pharmaceutical packaging materials. | 05 |
| | (c) | Write a Short note on BACPAC. | 05 |
