

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER-2 EXAMINATION – SUMMER-2019

Subject Code: MQA204T**Date: 03/06/2019****Subject Name: Pharmaceutical Manufacturing Technology****Time: 10:30 AM TO 01:30 PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1** (a) Discuss in-process quality control tests for suspensions and emulsions. **06**
(b) Write a note process automation for monitoring of parenteral manufacturing facility. **05**
(c) Describe principle of lyophilization technology. **05**
- Q.2** (a) Explain various factors affecting plant location. **06**
(b) Discuss general principles, and scheduling in production planning. **05**
(c) Write about special provision for storage requirements in plant layout for sterile and aseptic area. **05**
- Q.3** (a) Describe quality control test for glasses. **06**
(b) Discuss about evaluation of stability of packaging materials. **05**
(c) Explain quality control of packaging materials. **05**
- Q.4** (a) Write about advanced sterile product manufacturing technology. **06**
(b) Describe in-process quality control tests for solutions. **05**
(c) Write a note on various types of containers and closures for pharmaceuticals. **05**
- Q.5** (a) Short note: In-process quality control tests for tablets and capsules. **06**
(b) Explain various process of tablet production, and problems encountered in it. **05**
(c) Why tablet coating is required? Discuss types, application techniques and problems encountered in coating technology. **05**
- Q.6** (a) Write a note on risk assessments and minimization with help of QbD. **06**
(b) Short note: Drug-plastic interactions. **05**
(c) Describe briefly: QbD for drug substances, QbD for excipients and Analytical QbD. **05**
- Q.7** (a) Why QbD is required? Give advantages, elements and limitations of QbD. **06**
(b) Explain role of design of experiments. **05**
(c) Discuss PAT as a driver for improving quality and reducing cost in pharmaceutical manufacturing. **05**
