

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

**Subject Code: MPA203T****Date: 31/05/2019****Subject Name: Quality Control and Quality Assurance****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) Explain the difference between Quality Control and Quality Assurance activities. **06**
- (b) Describe the responsibilities of personnel working in a pharmaceutical manufacturing unit. **05**
- (c) Explain Q3C impurities guideline for residual solvent. **05**
- Q.2** (a) Discuss maintenance, retention of documented record. **06**
- (b) Write a note on cGMP guidelines according to schedule M. **05**
- (c) Write note on Distribution records **05**
- Q.3** (a) Enlist different module of CTD and Explain any Module in detail. **06**
- (b) Difference requirement of regulated and non regulated markets **05**
- (c) Write note on IPQC test for suppositories. **05**
- Q.4** (a) Explain the guidelines for sanitation of manufacturing premises. **06**
- (b) Discuss about release of finish product. **05**
- (c) Write note on importance of quality audit. **05**
- Q.5** (a) Write note on submission documents for regulators DMFs. **06**
- (b) Write good practices followed sampling of raw materials. **05**
- (c) Describe about CPCSEA guidelines in detail. **05**
- Q.6** (a) What are the current GMP guidelines for manufacturing of Parenteral products? **06**
- (b) Write note on finish product QC test for tablets. **05**
- (c) Write note on IPQC test for cream. **05**
- Q.7** (a) Write note on control of contamination as per GMP Guideline **06**
- (b) Write note on trade mark. **05**
- (c) How to write Standard operating procedures? **05**