



GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm - SEMESTER-I • EXAMINATION – SUMMER-2018

Subject Code: MQA102T

Date: 05/05/2018

Subject Name: QUALITY MANAGEMENT SYSTEM

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) | Define Quality. Briefly explain strategy and strategic quality management, mission and vision for quality, quality policy along with its objectives. | 08 |
| | (b) | Explain importance of cost of quality. Briefly explain categories of cost of quality, models of cost of quality, Optimizing costs and preventing cost of quality | 08 |
| Q.2 | (a) | Write a note on Risk assessment within the HACCP system | 06 |
| | (b) | Write a note on Quality Culture Benchmarking. | 05 |
| | (c) | Write a note on (i) Vendor Qualification (ii) Batch Review and Batch Release | 05 |
| Q.3 | (a) | Write a note on Total Quality Management (TQM). | 08 |
| | (b) | Explain following in quality management system:
(i) Self inspection (ii) IPQC | 08 |
| Q.4 | (a) | Write a note on McKinsey 7s model in quality management. | 06 |
| | (b) | Write a note on NABL Certification. | 05 |
| | (c) | Write a note on ICH guidelines for stability testing of drug substances and drug products. | 05 |
| Q.5 | (a) | Write a note on 'quality metrics' in pharmaceutical quality management | 08 |
| | (b) | Explain in brief following:
(i) Corrective & Preventive Actions (CAPA) in FDA
(ii) Out of Specifications (OOS) and Out of Trend (OOT). | 08 |
| Q. 6 | (a) | Write a note on Pharmaceutical Quality System ICH Q10. | 08 |
| | (b) | What is Statistical Process control (SPC)? Give its importance and advantages. Briefly explain implementing Statistical Process Control. | 08 |
| Q.7 | (a) | Explain principles of six sigma. Briefly explain ISO 9001:2008, ISO 9001:2015, ISO 14001:2004. | 08 |
| | (b) | Write a note on:
(i) OSHAS guidelines (ii) 21 CFR Part 11 | 08 |
