

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

Subject Code: MQA102T**Date: 30/05/2019****Subject Name: Quality Management System****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 McKinsey's 7s Management Model for an organization describing various hard and soft elements . | 06 |
| | (b) Define the followings: Quality Policy and Objectives; Mission and vision statement. . | 05 |
| | (c) Describe the cost of quality and categories thereof. | 05 |
| Q.2 | (a) What is the latest version of ISO 9001? Write a note on Documentation requirements as per ISO 9001. | 06 |
| | (b) Explain the benefits, basic principles and methodology of ISO 14000 family of standards. | 05 |
| | (c) Write a note on TQM with reference to pharmaceutical quality management. | 05 |
| Q.3 | (a) Write an account of Six System Inspection model of USFDA . Describe the importance and interrelation of Quality System with other five Systems. | 08 |
| | (b) Explain the terms OOT and OOS and how they are handled in pharmaceutical manufacturing and quality control unit. | 08 |
| Q.4 | (a) Differentiate between Corrective action & Preventive action and explain their importance in Quality Management System. | 06 |
| | (b) Enumerate parameters reviewed under Annual Product Review. | 05 |
| | (c) Enumerate parameters and documents considered for batch release and review. | 05 |
| Q.5 | (a) Enumerate ICH stability testing guidelines for new drug substances and product. Briefly describe the followings with respect to guidelines –Climatic Zone, Stress Testing, Storage Conditions, Evaluation of stability. | 08 |
| | (b) Define the term Quality, Quality System and Quality Risk Management. Enumerate different QRM tools. Describe seven steps to implement Hazard Analysis and Critical Control Point (HACCP). | 08 |
| Q. 6 | (a) Describe the scope of ICH Q8 guidelines. Explain the terms Critical Quality Attributes, Design space and Control strategy with respect to guideline | 08 |
| | (b) What is meant by Benchmarking? Write a note on types and process of benchmarking. Comment on limitations of benchmarking. | 08 |
| Q.7 | (a) Define statistical process control. Explain process capability and its mathematical expression as process capability index. | 06 |
| | (b) Write a note on process capability study. | 05 |
| | (c) What is meant by Quality Metrics? Enumerate different key performance indicators. | 05 |
