

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Ph. - SEMESTER-VII • EXAMINATION – WINTER -2021

Subject Code: BP706TT**Date: 03/12/2021****Subject Name: 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.

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| Q.1 | (a) Define & explain the concept of QA, QC and GMP. | 06 |
| | (b) Write detailed account on TQM. | 05 |
| | (c) Describe ISO 9000 in brief. | 05 |
| Q.2 | (a) Discuss briefly the overview of QSEM guidelines of ICH. Discuss specially Q-series guidelines. | 06 |
| | (b) Explain importance of Quality by design. Discuss elements of QBD program. | 05 |
| | (c) Discuss principles and procedures for NABL accreditation. | 05 |
| Q.3 | (a) Discuss responsibilities of personnel in Pharmaceutical organization. | 06 |
| | (b) Write the importance of training, hygiene and records of personnel in Pharmaceutical organization. | 05 |
| | (c) Explain design, construction and plant layout of sterile manufacturing plant. | 05 |
| Q.4 | (a) Write detailed account on quality control test for containers of various dosage forms. | 06 |
| | (b) Write a short note on Batch Formula Record & Master Formula Record. | 05 |
| | (c) Discuss selection and purchase specifications of equipments. | 05 |
| Q.5 | (a) Discuss evaluation of complaints and Handling of return goods. | 06 |
| | (b) Write descriptive note on SOP. | 05 |
| | (c) Discuss: Quality Audit, Quality Review and Quality documentation. | 05 |
| Q. 6 | (a) Write importance and scope of validation. Discuss qualification of UV-Visible Spectrophotometer. | 06 |
| | (b) Discuss general principles of Analytical method validation. | 05 |
| | (c) Write details on DQ, IQ, OQ and PQ. | 05 |
| Q.7 | (a) Write brief account on GLP. | 06 |
| | (b) Discuss protocols, Records and Reports for Conduct of a Nonclinical Laboratory study. | 05 |
| | (c) Write note on Good warehousing practice and material management. | 05 |
