

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.

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
