

Enrollment No./Seat No.:

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm - SEMESTER - VII EXAMINATION - WINTER 2025

Subject Code: BP706TT

Date: 21-11-2025

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.**

	Marks
Q.1 (a) What is QbD? Explain elements of QbD in detail.	06
(b) Write a note on Master Formula Record.	05
(c) Write in detail about protocol for conduct of nonclinical laboratory study.	05
Q.2 (a) Write a note on purchase specification and maintenance of store for raw materials.	06
(b) Discuss various quality control tests for secondary packaging materials.	05
(c) Write principles and procedures of NABL accreditation.	05
Q.3 (a) Write design, construction and plant layout of Pharmaceutical Industry.	06
(b) What is TQM? Explain the philosophies of TQM.	05
(c) Enlist different ICH guidelines. Discuss in brief about Quality guideline.	05
Q.4 (a) Discuss in brief : ISO 9000 and ISO 14000. Discuss various steps for its registration.	06
(b) Write a brief note on GLP.	05
(c) Write the importance of training, hygiene and records of personnel in Pharmaceutical organization.	05
Q.5 (a) Write various quality control test for glass and plastic containers.	06
(b) What is complaint? Explain its types and procedure for handling the complaint.	05
(c) Discuss about maintenance of sterile areas in premises.	05
Q.6 (a) Write a detailed note on SOP.	06
(b) Discuss responsibilities of personnel in Pharmaceutical organization.	05
(c) Write note on good warehousing practice.	05
Q.7 (a) Define calibration. Discuss the qualification of UV-Visible spectrophotometer.	06
(b) Write a note on analytical method validation parameters.	05
(c) Discuss: Quality Audit and Distribution records.	05
