

GUJARAT TECHNOLOGICAL UNIVERSITY**B.PHARM - SEMESTER-7 EXAMINATION – SUMMER-2024****Subject Code:BP706TT****Date: 16/05/2024****Subject Name: Quality Assurance****Time: 02.30 p.m. to 5.30 p.m.****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) Write a note on Master Formula Record.	06
	(b) Write detailed account on TQM.	05
	(c) What is QbD? Explain different tools of QbD.	05
Q.2	(a) Discuss various quality control tests for secondary packaging materials.	06
	(b) Discuss about DQ, IQ, OQ and PQ.	05
	(c) Write a short note on NABL accreditation.	05
Q.3	(a) Write down a scope of validation. Discuss qualification of UV-Visible spectrophotometer.	06
	(b) Explain purchase specification and maintenance of store for raw material.	05
	(c) Write in detail about protocol for conduct of nonclinical laboratory study.	05
Q.4	(a) Write a short note on evaluation of complaints and handling of return good.	06
	(b) Discuss general principles of calibration and explain calibration of pH meter.	05
	(c) Explain the objectives and scope of GLP.	05
Q.5	(a) Enlist different ICH guideline and discuss guideline for stability testing.	06
	(b) Write descriptive note on SOP.	05
	(c) Discuss: Quality Audit and distribution records.	05
Q. 6	(a) Discuss general principles of Analytical method validation.	06
	(b) Describe ISO 9000 in brief.	05
	(c) Write descriptive note on Good warehousing practice.	05
Q.7	(a) Discuss elements of QBD program.	06
	(b) Explain construction and layout of sterile manufacturing plant.	05
	(c) Discuss the regulatory requirements for design, construction and plant layout of pharmaceutical manufacturing facility.	05
