

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- 7 EXAMINATION – SUMMER -2023

Subject Code: BP706TT**Date: 28/06/2023****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 principles and procedures NABL accreditation	06
	(b) Write difference between Q.A and Q.C	05
	(c) Write short note on TQM	05
Q.2	(a) Write design, construction and plant layout of pharmaceutical industry.	06
	(b) Write note on utilities and maintenance of sterile areas	05
	(c) Write note on maintenance of stores for raw materials.	05
Q.3	(a) Write note on protocol for conduct of a nonclinical laboratory study	06
	(b) Write various quality control test for containers and rubber closures	05
	(c) Write note on disqualification of testing facilities	05
Q.4	(a) Write note on master formula record	06
	(b) Write note on SOP	05
	(c) Write the procedure for complaints evaluation	05
Q.5	(a) What is process validation? Explain prospective and retrospective validation	06
	(b) Discuss DQ and IQ in process validation.	05
	(c) Explain revalidation criteria.	05
Q. 6	(a) What is validation master plan? Explain its importance in Setting up of new manufacturing facility	06
	(b) Discuss analytical method validation according to ICH Guidelines	05
	(c) Write note on Quality audit	05
Q.7	(a) Write a note on qualification of UV-Visible spectrophotometer	06
	(b) Write note on good warehousing practice	05
	(c) Write short note on: ISO14000	05
