

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Ph. - SEMESTER– VII• EXAMINATION – SUMMER -2022

Subject Code: BP706TT**Date: 13/06/2022****Subject Name: Quality Assurance****Time: 02:30pm to 05:30pm****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) Describe the procedure of NABL accreditation in India	06
	(b) Define QbD. What are its advantages?	05
	(c) Define Total Quality Management. Explain its elements	05
Q.2	(a) Explain the terms (i) ISO 9000 (ii) QSEM	06
	(b) Give brief account on training of personnel in pharmaceutical industry	05
	(c) Explain the plant layout for sterile facility in pharmaceutical industry	05
Q.3	(a) Enlists the factors to be considered in selection and purchase of equipments	06
	(b) Describe the maintenance of stores for raw materials	05
	(c) What do you understand by disqualification of testing facilities?	05
Q.4	(a) Explain the quality control tests performed for containers	06
	(b) Describe general protocol for conduct of a nonclinical laboratory study.	05
	(c) What are the requirements for the testing facility as per GLP?	05
Q.5	(a) What is a complaint? Give an overview on recalling the pharmaceutical product	06
	(b) Give brief account on distribution records	05
	(c) Write in brief (i) Good warehousing practice (ii) Stability testing as per ICH	05
Q. 6	(a) What do you mean by SOP? Explain the importance of SOP in pharmaceutical industries	06
	(b) Define Quality audit. Explain the types of Quality audit	05
	(c) What is Batch Formula Record? What does it include?	05
Q.7	(a) Describe the procedure for two point Calibration of pH meter	06
	(b) Enumerate different type of validations. Explain prospective validation	05
	(c) Enlist the parameters to be checked for method validation. Explain any two	05
