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

Subject Code: BP706TT			Date:	13/06/2022	
Subject Name: Quality AssuranceTime: 02:30pm to 05:30pmTotal Marks: 80Instructions:1. Attempt any five questions.1. Attempt any five questions.2. Make suitable assumptions wherever necessary.3. Figures to the right indicate full marks.					
Q.1	(a) (b) (c)	Describe the procedure of NABL accreditation in India Define QbD. What are its advantages? Define Total Quality Management. Explain its elements			06 05 05
Q.2	(a) (b) (c)	Explain the terms (i) ISO 9000 (ii) QSEM Give brief account on training of personnel in pharmaceutic Explain the plant layout for sterile facility in pharmaceutica		•	06 05 05
Q.3	(a) (b) (c)	Enlists the factors to be considered in selection and purchas Describe the maintenance of stores for raw materials What do you understand by disqualification of testing facili	f stores for raw materials		06 05 05
Q.4	(a) (b) (c)	Explain the quality control tests performed for containers Describe general protocol for conduct of a nonclinical labo What are the requirements for the testing facility as per GL	•	tudy.	06 05 05
Q.5	(a) (b) (c)	What is a complaint? Give an overview on recalling the ph Give brief account on distribution records Write in brief (i) Good warehousing practice (ii) Stability to		-	06 05 05
Q. 6	(a) (b) (c)	What do you mean by SOP? Explain the importance of SO industries Define Quality audit. Explain the types of Quality audit What is Batch Formula Record? What does it include?	P in pha	rmaceutical	06 05 05
Q.7	(a) (b) (c)	Describe the procedure for two point Calibration of pH me Enumerate different type of validations. Explain prospective Enlist the parameters to be checked for method validation.	ve valida		06 05 05
