Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER–7 EXAMINATION – SUMMER-2025

Subject Code: BP706TT **Date: 20/05/2025**
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)**	Enlist analytical method validation parameters for assay of drug products. Describe LOQ and accuracy with their evaluation techniques as per ICH.	**06**
	(b)	What is pharmaceutical waste? Write a note on waste disposal procedures and the records to be kept for them.	**05**
	(c)	What is the purpose of ICH guidelines? Write down the process of harmonization.	**05**
Q.2	**(a)**	What is QbD? Explain elements of QbD in detail.	**06**
	(b)	What is NABL accreditation? Discuss its importance.	**05**
	(c)	Write objectives of GLP? Discuss in brief the key points in GLP.	**05**
Q.3	**(a)**	Draw a sample plant layout for pharmaceutical industry along with space required as per schedule M.	**06**
	(b)	Discuss maintenance of sterile area and control of contamination as a part of plant premises.	**05**
	(c)	Why product to be recall? Write briefly about procedures to be followed for recalling a product.	**05**
Q.4	**(a)**	Write a note on purchase specification and maintenance of store for raw materials.	**06**
	(b)	Write a note on ICH stability testing guideline.	**05**
	(c)	Write in brief about SOP.	**05**
Q.5	**(a)**	Write is the difference between QA and QC. How QA, QC and GMP are correlated?	**06**
	(b)	What is TQM? Explained various elements of TQM.	**05**
	(c)	Write a note on Master Formula Record.	**05**
Q. 6	**(a)**	Describe the advantages and disadvantages of plastic containers with that of glass container. Discuss QC tests carried out on plastic containers.	**06**
	(b)	Discuss general protocol for conduct of a Nonclinical laboratory study	**05**
	(c)	Discuss BMR and its auditing with references to cGMP.	**05**
Q.7	**(a)**	Write the procedure for complaints evaluation	**06**
	(b)	Write note on disqualification of testing facilities	**05**
	(c)	Write short note on: ISO14000	**05**

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