Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph. – SEMESTER-VII • EXAMINATION – WINTER-2022

Subject Code: BP706TT **Date: 31/12/2022**

Subject Name: Quality Assurance

Time: 10:30 am to 01:30 pm **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 importance and scope of validation. Discuss qualification of UV-Visible Spectrophotometer.	**06**
	(b)	Discuss validation of analytical procedures.	**05**
	(c)	What is pharmaceutical waste? Write a note on waste disposal procedures and the records to be kept for them.	**05**
Q.2	**(a)**	Enlist different ICH guidelines. Discuss in brief about Quality guideline.	**06**
	(b)	What is QA? Differences of QA and QC.	**05**
	(c)	Write a detailed note on TQM.	**05**
Q.3	**(a)**	Write in brief about SOP.	**06**
	(b)	Give brief note on ISO 9000 & ISO 14000? Discuss various steps for its registration.	**05**
	(c)	Explain importance of Quality by design. Discuss elements of QBD program.	**05**
Q.4	**(a)**	Draw a sample plant layout for pharmaceutical industry along with space required as per schedule M.	**06**
	(b)	Write a note on Master Formula Record.	**05**
	(c)	What is a complaint? Discuss how to handle returns goods.	**05**
Q.5	**(a)**	Write a brief note on GLP.	**06**
	(b)	Discuss responsibilities of personnel in Pharmaceutical organization.	**05**
	(c)	What does GMP cover? Write main principles of GMP for pharmaceutical products.	**05**
Q. 6	**(a)**	Write details on DQ, IQ, OQ and PQ.	**06**
	(b)	Write the importance of training, hygiene and records of personnel in Pharmaceutical organization.	**05**
	(c)	Define calibration. Discuss principles of calibration.	**05**
Q.7	**(a)**	Discuss about maintenance of sterile areas in premises.	**06**
	(b)	Discuss briefly good warehousing practices for different materials used in pharmaceutical industry.	**05**
	(c)	Explain principles of NABL accreditation?	**05**

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