Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– 7 EXAMINATION – WINTER -2024

Subject Code: BP702TT Date: 22-11-2024

Subject Name: Industrial Pharmacy II

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 a note on personnel requirement, space requirement and responsibility in terms of pilot plant studies.	**06**
	(b)	Write a note on SUPAC for IR dosage form.	**05**
	(c)	Write a note on pilot plant scale up studies for liquid dosage form.	**05**
Q.2	**(a)**	Differentiate IND and NDA. Brief considerations of IND.	**06**
	(b)	Explain roles and responsibilities of regulatory affairs.	**05**
	(c)	Write a note on clinical research protocol submission.	**05**
Q.3	**(a)**	Briefly explain the brief Overview of Quality by Design Process.	**06**
	(b)	Enumerate and briefly explain the various tools used in Total quality management.	**05**
	(c)	Explain the six sigma methodology implementation.	**05**
Q.4	**(a)**	What is CDSCO? Explain its role in regulatory requirement.	**06**
	(b)	Brief about organization and responsibilities of COPP.	**05**
	(c)	Explain Regulatory requirements and approval procedures for New Drugs.	**05**
Q.5	**(a)**	Explain quality risk management in technology transfer.	**06**
	(b)	Describe steps in technology transfer process for pharmaceutical industry	**05**
	(c)	Brief various practical aspects and problems involved in commercialization process.	**05**
Q. 6	**(a)**	Explain importance of biostatistics in pharmaceutical product development.	**06**
	(b)	Describe in detail elements of ISO 9000.	**05**
	(c)	Write a note on platform technology.	**05**
Q.7	**(a)**	Write a note on data presentation for submission to FDA.	**06**
	(b)	Mention approved agencies for TT and explain them.	**05**
	(c)	Describe the investigator’s brochure for IND.	**05**

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