Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– 7 EXAMINATION – SUMMER -2023

Subject Code: BP702TT **Date: 20/06/2023**

Subject Name: Industrial Pharmacy II

Time:02.30 p.m. to 5.30 p.m. **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)**	Discuss platform technology for scale-up techniques with appropriate examples.	**06**
	(b)	Write a note on various technology transfer agencies in India.	**05**
	(c)	Write a detailed note on various levels of changes in SUPAC guidelines.	**05**
Q.2	**(a)**	Write in brief about qualification and validation in technology transfer.	**06**
	(b)	Describe the documentation requirement for transferring the technology from R & D to the manufacturing level.	**05**
	(c)	Write a note on COPP.	**05**
Q.3	**(a)**	Write on Quality Risk Management.	**06**
	(b)	Explain the importance of the Investigator's Brochure.	**05**
	(c)	Write a note on Out of Specifications (OOS).	**05**
Q.4	**(a)**	What is Six Sigma? Discuss the importance of the Six Sigma concept	**06**
	(b)	Introduce ISO 9000 as a series of quality system standards.	**05**
	(c)	Describe the basic concepts of TQM.	**05**
Q.5	**(a)**	Describe the procedure for new drug approval from CDSCO in India.	**06**
	(b)	Explain the purpose, benefits, and elements of Total Quality Management	**05**
	(c)	Explain the Organization and Responsibilities of the State Licensing Authority in India.	**05**
Q. 6	**(a)**	Describe pilot plant scale-up considerations for semi-solid dosage forms.	**06**
	(b)	How Bioequivalence is documented?	**05**
	(c)	Write in brief about APCTD and NRDC.	**05**
Q.7	**(a)**	Describe Pilot plant scale-up considerations for solid dosage forms.	**06**
	(b)	Write a note on TIFAC	**05**
	(c)	Discuss the responsibilities of regulatory affairs professionals.	**05**

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