Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: BP702TT **Date:03/06/2022**

Subject Name: Industrial Pharmacy II

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)**	What is Six Sigma. Describe the importance of six sigma in achieving "zero defect"?	**06**
	(b)	Describe in general out of specifications with respect to quality management?	**05**
	(c)	Introduce ISO 9000 as a series of quality system standards.	**05**
Q.2	**(a)**	Describe documentation required for changes is batch size as per SUPAC guidelines.	**06**
	(b)	Discuss pilot plant scale up consideration for semi-solids.	**05**
	(c)	Write a note on significance of space requirement for scale up techniques.	**05**
Q.3	**(a)**	Discuss platform technology for scale up techniques with appropriate examples.	**06**
	(b)	Describe importance of raw materials with respect to pilot plant scale up.	**05**
	(c)	Write a note on certificate of pharmaceutical product (COPP).	**05**
Q.4	**(a)**	Discuss the scope of WHO guidelines on transfer of technology in pharmaceutical manufacturing.	**06**
	(b)	Write a detailed note on various level of changes in SUPAC guidelines.	**05**
	(c)	Describe the organization and responsibilities of CDSCO.	**05**
Q.5	**(a)**	Write a note on various agencies involved in technology transfer in India.	**06**
	(b)	Discuss technology transfer related documentation for confidentiality agreement.	**05**
	(c)	Briefly discuss approval procedures for new drugs in CDSCO.	**05**
Q. 6	**(a)**	Introduce quality risk management with respect to technology transfer.	**06**
	(b)	Explain the importance of Investigator's Brochure.	**05**
	(c)	Convey historical overview of Regulatory Affairs.	**05**
Q.7	**(a)**	What is IND Application. Discuss Emergency use IND Application.	**06**
	(b)	Briefly describe Management of Clinical trials.	**05**
	(c)	Describe the responsibility of regulatory affairs professionals.	**05**

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