Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: BP702TT Date: 03/01/2023

Subject Name: INDUSTRIAL PHARMACY-II

Time: 10:30am to 01:30pm 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)**	Write about the uses of Platform Technology.	**06**
	(b)	Write on Quality Risk Management.	**05**
	(c)	Discuss responsibilities of regulatory affairs professionals.	**05**
Q.2	**(a)**	Discuss historical overview of regulatory affairs.	**06**
	(b)	Write a note on TIFAC.	**05**
	(c)	Write in brief about APCTD and NRDC.	**05**
Q.3	**(a)**	Write a note on SUPAC guidelines.	**06**
	(b)	Write the protocol to conduct non clinical testing.	**05**
	(c)	Discuss Investigational New Drug (IND) Application	**05**
Q.4	**(a)**	Describe pilot plant scale up considerations for semi-solid dosage forms.	**06**
	(b)	What are the objectives and significance of pilot plants?	**05**
	(c)	Write a note on Total Quality Management.	**05**
Q.5	**(a)**	Write in brief about qualification and validation in technology transfer.	**06**
	(b)	Discuss about technology transfer protocol.	**05**
	(c)	Write a note on Certificate of Pharmaceutical Product (COPP).	**05**
Q. 6	**(a)**	Write about significance of documentation in technology development and transfer.	**06**
	(b)	Write a note on Six sigma as a tool for quality management.	**05**
	(c)	How Bioequivalence are documented?	**05**
Q.7	**(a)**	Describe Pilot plant scale up considerations for solid dosage forms.	**06**
	(b)	Write about the role of regulatory affairs department in industry.	**05**
	(c)	Discuss selection of pharmaceutical packaging materials.	**05**

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