Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code:BP702TT Date: 02/05/2024

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)**	What is pilot plan study? Discuss objective and steps for pilot plan scale up study.	**06**
	(b)	Write a detailed note on various level of changes in SUPAC guidelines.	**05**
	(c)	Discuss platform technology for scale up techniques with appropriate examples.	**05**
Q.2	**(a)**	Define IND. What information is to submitted with IND application? How can IND application be withdraw?	**06**
	(b)	Justify role of biostatistics in Pharmaceutical product development	**05**
	(c)	Discuss general consideration for space requirement for scale up techniques.	**05**
Q.3	**(a)**	Describe the responsibility of regulatory affairs professionals	**06**
	(b)	Mention the goals of NDA. Discuss the general requirements for filing NDA.	**05**
	(c)	Describe the content and format of NDA.	**05**
Q.4	**(a)**	Describe the organization and responsibilities of CDSCO.	**06**
	(b)	Explain Regulatory requirements and approval procedures for New drug.	**05**
	(c)	Write a note on Certificate of Pharmaceutical Product.	**05**
Q.5	**(a)**	Explain benefits and key elements QbD.	**06**
	(b)	Write short note on Six sigma as a tool for quality management.	**05**
	(c)	Explain ISO 9000 series of quality systems standards for pharmaceutical product.	**05**
Q. 6	**(a)**	Give classification, advantage and disadvantages of technology transfer.	**06**
	(b)	What is granularity? Discuss the consideration in the granularity of TT process?	**05**
	(c)	What is SUPAC? Give SUPAC guidelines for modified release dosages form.	**05**
Q.7	**(a)**	Compare the following: a) Responsibilities of SU's and RU's b) Do's and Don't of TT agreements.	**06**
	(b)	Write in brief about APCTD and NRDC.	**05**
	(c)	Explain the principles of technology transfer. Discuss the technical and regulatory gap assessment during the process.	**05**

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