Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM – SEMESTER – 7 EXAMINATION – SUMMER-2025

Subject Code: BP702TT **Date: 13-05-2025**

Subject Name: Industrial Pharmacy II

Time: 02.30 PM TO 05.30 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)**	Explain the type of changes applicable under SUPAC IR guidelines.	**06**
	(b)	Enlist and explain consideration for pilot plan scale-up for oral solid dosage form.	**05**
	(c)	Explain in details factors to be considered for technology transfer from research and development to production in pharmaceutical industry.	**05**
Q.2	**(a)**	Explain in detail various phases of a technology transfer project.	**06**
	(b)	Write a note on the role and responsibilities of regulatory affairs professionals in pharmaceutical industries.	**05**
	(c)	Define IND. Explain various types of IND according to the US FDA with suitable examples.	**05**
Q.3	**(a)**	Explain the content and importance of the Investigator's Brochure (IB) in clinical studies.	**06**
	(b)	Explain the concept of Quality by Design (QbD) with respect to the development of pharmaceutical products.	**05**
	(c)	Write a note on the scope and importance of accreditation under NABL in India.	**05**
Q.4	**(a)**	Explain the organizational structure and function of CDSCO.	**06**
	(b)	Explain the composition and function of state-level regulatory agencies for pharmaceutical products in India.	**05**
	(c)	Explain the quality management principles related to ISO 9000 series.	**05**
Q.5	**(a)**	Write a note on regulatory requirements and approval procedures for New Drugs in India	**06**
	(b)	What is the Six Sigma concept? Explain the characteristics, objectives and principles of Six Sigma in the context of the pharmaceutical industry.	**05**
	(c)	Explain in detail important aspects of technology transfer agreements for pharmaceutical products.	**05**
Q. 6	**(a)**	Explain non-clinical studies for new drug development.	**06**
	(b)	Write a note on the function of TIFAC in the context of technology transfer.	**05**
	(c)	Write a note on platform technology with respect to pharmaceutical products with suitable examples.	**05**
Q.7	**(a)**	Write a note on the significance of space requirement for scale-up techniques.	**06**
	(b)	Discuss confidentiality agreements in Technology Transfer.	**05**
	(c)	What is quality risk management system? Explain its principle, scope, and tools to implement it with respect to the pharmaceutical industry.	**05**

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