Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph -SEMESTER–VII • EXAMINATION – WINTER -2020

Subject Code: BP702TT **Date: 04/01/2021**

Subject Name: INDUSTRIAL PHARMACY II

Time: 10:30AM To 12:30PM **Total Marks: 54**

Instructions:

1. **Attempt any THREE questions from Q-1 to Q-6.**
2. **Q.7 is compulsory to attempt.**
3. **Make suitable assumptions wherever necessary.**
4. **Figures to the right indicate full marks.**

Q.1	**(a)**	Describe the procedure for new drug approval from CDSCO in India.	**06**
	(b)	Describe the investigator's brochure for IND.	**05**
	(c)	Write short note on Six sigma as a tool for quality management.	**05**
Q.2	**(a)**	Write the benefits of ISO to an organization. Write a note on ISO 9001:2008.	**06**
	(b)	Describe the basic concepts of TQM.	**05**
	(c)	Discuss change control in quality management system.	**05**
Q.3	**(a)**	Explain in brief SUPAC guidelines for immediate release solid oral dosage forms.	**06**
	(b)	Write a note on platform technology citing appropriate example.	**05**
	(c)	Write briefly on NABL certification.	**05**
Q.4	**(a)**	Write a detail note on pilot plant scale up of tablets.	**06**
	(b)	Discuss selection of pharmaceutical packaging materials.	**05**
	(c)	Explain the documentation in technology transfer.	**05**
Q.5	**(a)**	Write a note on "Approved regulatory bodies and agencies of India for TT".	**06**
	(b)	Write about role of regulatory affairs department.	**05**
	(c)	Write a note on COPP.	**05**
Q. 6	**(a)**	What is Technology transfer? Write importance of Technology transfer in pharmaceutical industry.	**06**
	(b)	Discuss in detail various factors affecting design of a pharmaceutical pilot plant facility.	**05**
	(c)	Write a note on clinical research protocol.	**05**
Q.7	**(a)**	Write a brief note on qualification and validation in technology transfer.	**06**
		OR	
	(a)	Write a note on state licensing authority under Indian regulatory requirements.	**06**
		OR	
	(a)	Write the protocol to conduct non clinical testing.	**06**

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