Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph. - SEMESTER–VII • EXAMINATION – WINTER -2021

Subject Code:BP702TT **Date: 26/11/2021**

Subject Name: Industrial Pharmacy II

Time: 10:30 AM TO 01:30 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)**	Define Pilot plant and scale up. Discuss importance of pilot plant study.	**06**
	(b)	Discuss various levels of changes under distinct headings of any two changes in context to SUPAC - Immediate Release Solid Oral Dosage Form.	**05**
	(c)	What is pilot plan study? Discuss objective and steps for pilot plan scale up study.	**05**
Q.2	**(a)**	Write a note on Certificate of Pharmaceutical Product (COPP).	**06**
	(b)	Describe documentation requirement for transfer the technology from R & D to manufacture level.	**05**
	(c)	Discuss SUPAC guidelines for semisolid dosage forms with reference to the components and composition changes.	**05**
Q.3	**(a)**	What is Investigational New Drug (IND) Application? Explain Requirement and types of an IND.	**06**
	(b)	Write a note on ANDA.	**05**
	(c)	Explain Clinical trial Management Studies in details.	**05**
Q.4	**(a)**	Explain ISO 9000 series of quality systems standards for pharmaceutical product.	**06**
	(b)	Write a note on Out of Specifications (OOS).	**05**
	(c)	Explain purpose, benefits and elements Total Quality Management.	**05**
Q.5	**(a)**	Explain review process for New Drug Application (NDA).	**06**
	(b)	Write a note on scope and organization management as per WHO guideline.	**05**
	(c)	Describe steps in technology transfer process for pharmaceutical industry.	**05**
Q. 6	**(a)**	What is CDSCO? Explain function of CDSCO in details.	**06**
	(b)	Write a note on Certificate of Pharmaceutical Product (COPP).	**05**
	(c)	Explain Regulatory requirements and approval procedures for New Drugs in India.	**05**
Q.7	**(a)**	Write a note on Change control in pharmaceutical company with examples.	**06**
	(b)	Explain Organization and Responsibilities of State Licensing Authority in India.	**05**
	(c)	How to Data Presentation for FDA Submissions? Explain in details.	**05**

****