GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm - SEMESTER– VII• EXAMINATION – SUMMER -2021

Subject Code: BP702TT   **Date: 04/08/2021**
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 a detailed note on various level of changes in SUPAC guidelines.	**06**
	(b)	Discuss pilot plant scale up consideration for oral liquids.	**05**
	(c)	Discuss general consideration for space requirement for scale up techniques.	**05**
Q.2	**(a)**	Discuss various documentation required for changes is batch size as per SUPAC guidelines.	**06**
	(b)	Introduce platform technology with respect to pilot plant scale up technique.	**05**
	(c)	What is Certificate of Pharmaceutical Product?	**05**
Q.3	**(a)**	Discuss the scope of WHO guidelines on transfer of technology in pharmaceutical manufacturing.	**06**
	(b)	Briefly describe technology transfer protocol.	**05**
	(c)	Write a note on various technology transfer agencies in India.	**05**
Q.4	**(a)**	Discuss confidentiality agreement in Technology Transfer.	**06**
	(b)	Write in brief about Quality Risk Management with respect to Technology Transfer.	**05**
	(c)	Describe in brief responsibilities of CDSCO.	**05**
Q.5	**(a)**	What is IND Application. Discuss Emergency use IND Application.	**06**
	(b)	Convey historical overview of Regulatory Affairs.	**05**
	(c)	Briefly describe Management of Clinical trials.	**05**
Q. 6	**(a)**	Describe the responsibility of regulatory affairs professionals.	**06**
	(b)	Describe the importance of Investigator's Brochure.	**05**
	(c)	Briefly discuss approval procedures for new drugs.	**05**
Q.7	**(a)**	What is Six Sigma? Discuss the importance of Six Sigma concept.	**06**
	(b)	Write a brief note on ISO 9000 series of quality standards	**05**
	(c)	Write a note on procedure for change control.	**05**

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