Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – SUMMER • 2014

Subject Code: 930104 **Date: 22-05-2014**

Subject Name: Validation and Product Development

Time: 02:30 pm - 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)**	What is instrument validation? Give a detailed account on installation qualification.	**06**
	(b)	Discuss cleaning validation in pharma industry.	**05**
	(c)	How HPLC will be validated?	**05**
Q.2	**(a)**	Discuss analytical method validation according to ICH guideline. Explain precision in detail.	**06**
	(b)	Enlist the differences between Validation Protocol and Validation Master Plan.	**05**
	(c)	Explain in brief Vendor Certification.	**05**
Q.3	**(a)**	Discuss in detail IQ, OQ and PQ for Hot Air Oven.	**06**
	(b)	Write in short about HVAC system validation.	**05**
	(c)	Discuss the criteria for validation of tablet punching machine.	**05**
Q.4	**(a)**	What is process validation? Discuss prospective process validation in detail.	**06**
	(b)	Discuss revalidation.	**05**
	(c)	Write a note on validation of Dissolution Test Apparatus.	**05**
Q.5	**(a)**	Discuss the manufacturing process design, development and in process control for liquid orals.	**06**
	(b)	Draw the detailed cause and effect diagram for ointment manufacturing.	**05**
	(c)	Discuss unit operation along with their process variables for hard gelatin capsules.	**05**
Q.6	**(a)**	What is SOP? Give importance of it? Describe the SOP for Dissolution Test Apparatus.	**06**
	(b)	Explain in brief the variables used to monitor wet granulation step.	**05**
	(c)	Explain pilot scale up operation.	**05**
Q.7	**(a)**	Describe in detail Validation of Pharmaceutical Water Systems.	**06**
	(b)	Write in short about Computer System Validation.	**05**
	(c)	Write a short-note on Aseptic area validation.	**05**

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