Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – WINTER • 2015

Subject Code: 930104 **Date: 08-12-2015**

Subject Name: Validation and Product Development

Time: 10:30 am - 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)**	Why analytical method validation is required? Enlist method performance parameters for different type of analytical procedures and explain how will you assure that the developed method is accurate and precise?	**06**
	(b)	Explain: system suitability testing, calibration, ruggedness, revalidation, cleaning verification.	**05**
	(c)	What is validation and explain its scope and advantages to the pharmaceutical industry.	**05**
Q.2	**(a)**	Explain design qualification, installation qualification and explain under what conditions you will perform requalification of equipment.	**06**
	(b)	Write a brief note on user requirement specification.	**05**
	(c)	Describe in detail calibration master plan.	**05**
Q.3	**(a)**	Describe validation of HVAC system in sterile manufacturing area.	**06**
	(b)	Write a brief note on computer system validation.	**05**
	(c)	Describe calibration of UV-visible spectrophotometer along with its importance.	**05**
Q.4	**(a)**	Explain the Cause and Effect diagram for process of tablet manufacturing.	**06**
	(b)	Explain flow chart with critical process parameters for product development of liquid orals.	**05**
	(c)	Describe in detail various elements of cleaning validation.	**05**
Q.5	**(a)**	Describe manufacturing process, in process controls and finished product specifications for ophthalmic preparations.	**06**
	(b)	Write a detailed note on Vendor certification.	**05**
	(c)	Describe the prospective validation of capsule formulation.	**05**
Q. 6	**(a)**	Explain the requirements of scale-up and post-approval changes for immediate release dosage form.	**06**
	(b)	Explain retrospective validation taking one example of pharmaceutical formulation in detail.	**05**
	(c)	Describe briefly qualification of tablet compression machine.	**05**
Q.7	**(a)**	Explain OQ and PQ phase for qualification of fluid bed dryer.	**06**
	(b)	Write a detailed note on validation of pharmaceutical water system.	**05**
	(c)	Describe in detail method transfer.	**05**

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