Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-III–EXAMINATION – MAY 2012

Subject code: 930104 Date: 18/05/2012

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)	Define and explain i) Process validation ii) D- Value iii) F- Value	**06**
	(b)	Explain pilot scale up operation.	**05**
	(c)	Discuss design and installation qualification in process validation.	**05**
Q.2	(a)	Discuss in detail the prospective process validation.	**06**
	(b)	What do you understand by retrospective validation? How it can be conducted?	**05**
	(c)	Define and explain i) concurrent validation ii) revalidation	**05**
Q.3	(a)	Write short note on validation master plan.	**06**
	(b)	Describe validation parameters of HVAC system.	**05**
	(c)	Discuss validation procedure for pharmaceutical water system.	**05**
Q.4	(a)	Explain the basic principles involved in validation of sterile products	**06**
	(b)	Write a short note on validation of dry heat sterilization.	**05**
	(c)	Discuss the validation process for fluid bed and tray dryer.	**05**
Q.5	(a)	What precaution is necessary for validation of solid dosage form?	**06**
	(b)	Discuss the various guidelines for process validation of solid dosage form.	**05**
	(c)	Discuss the criteria for validation of tablet machine and capsule filling machine.	**05**
Q. 6	(a)	Discuss the criteria for computer system validation, which controlling the manufacturing process.	**06**
	(b)	Write short note on vendor certificate.	**05**
	(c)	Write short note on validation of dissolution test apparatus.	**05**
Q.7	(a)	Discuss SUPAC guideline.	**06**
	(b)	What steps involve in analytical method validation?	**05**
	(c)	What steps involve in validation of cleaning process?	**05**

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