

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.

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|-------------|-----|---|-----------|
| Q.1 | (a) | Define and explain | 06 |
| | | i) Process validation | |
| | | ii) D- Value | |
| | | iii) F- Value | |
| | (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 | 05 |
| | | i) concurrent validation | |
| | | ii) revalidation | |
| 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 |
