

GUJARAT TECHNOLOGICAL UNIVERSITY
M. PHARM. - SEMESTER – III • EXAMINATION – WINTER 2012

Subject code: 930104**Date: 23/11/2012****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) What is validation? Give a detailed account on installation qualification. | 06 |
| | (b) Write a note on Validation Master Plan. | 05 |
| | (c) Explain the importance of cleaning validation in pharma industry. | 05 |
| Q.2 | (a) Enlist various parameters to be evaluated for analytical method validation. Explain any one of them in detail. | 06 |
| | (b) How will you validate HPLC? | 05 |
| | (c) Write a note on validation of Dissolution Test Apparatus. | 05 |
| Q.3 | (a) Describe the procedure for validation of Autoclave. | 06 |
| | (b) Discuss the significance of equipment validation in pharma industry. | 05 |
| | (c) Give a brief account on Validation of integrated lines by media fill test. | 05 |
| Q.4 | (a) Discuss the types of Process Validation. | 06 |
| | (b) Explain in brief the variables used to monitor wet granulation step. | 05 |
| | (c) Describe the steps followed for the process validation of ointment. | 05 |
| Q.5 | (a) Describe the manufacturing process design and development as well as in process control for liquid orals. | 06 |
| | (b) Describe unit operation along with their process variables for hard gelatin capsules. | 05 |
| | (c) Write short note on Scale-up operation. | 05 |
| Q. 6 | (a) Describe in detail Validation of Pharmaceutical Water systems. | 06 |
| | (b) Give a brief account on Calibration Master Plan. | 05 |
| | (c) Write a short note on Validation of HVAC. | 05 |
| Q.7 | (a) Explain the importance of Computer System Validation in controlling the manufacturing process. | 06 |
| | (b) Discuss Validation Protocol Format. | 05 |
| | (c) Explain in brief Vendor Certification. | 05 |
