

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 |
