

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER-3 EXAMINATION – SUMMER-2019

Subject Code: 930104**Date: 29/05/2019****Subject Name: Validation And Product Development****Time: 02:30 PM TO 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.

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| Q.1 | (a) Define the following terms: Calibration, Commissioning, Qualification, Validation protocol, Worst case, Verification. | 06 |
| | (b) Explain different stages of facility and equipment qualification. | 05 |
| | (c) Write a note on Validation Master Plan. | 05 |
| Q.2 | (a) Discuss the types of Process Validation. | 06 |
| | (b) Define and explain Design qualification and calibration. | 05 |
| | (c) Write a note on validation of Fluid Bed Dryer. | 05 |
| Q.3 | (a) Discuss the significance of equipment validation in pharma industry. | 06 |
| | (b) Discuss validation parameters of HVAC system. | 05 |
| | (c) What is Protocol? Give the general protocol format for Prospective Process Validation. | 05 |
| Q.4 | (a) What do you understand regarding cleaning validation? Why it is necessary? | 06 |
| | (b) Write a note on Validation of HPLC. | 05 |
| | (c) Discuss in detail regarding validation of Dissolution Test Apparatus. | 05 |
| Q.5 | (a) Describe in detail Validation of Pharmaceutical Water Systems. | 06 |
| | (b) Explain pilot scale up operation. | 05 |
| | (c) Write short note on vendor certificate. | 05 |
| Q. 6 | (a) Explain different types of pharmaceutical waters. Draw a diagram of purified water generation, storage and distribution system. | 06 |
| | (b) What do you understand regarding revalidation? Discuss merits and demerits of revalidation. | 05 |
| | (c) Write note on packing material for parenteral product. | 05 |
| Q.7 | (a) Describe validation of UV-VIS spectrophotometer. | 06 |
| | (b) Describe briefly qualification of tablet compression machine. | 05 |
| | (c) Write in short about Computer System Validation. | 05 |
