

GUJARAT TECHNOLOGICAL UNIVERSITY
M. PHARM. - SEMESTER– II EXAMINATION – SUMMER 2016

Subject Code: 1921502**Date: 21/05/2016****Subject Name: GMP, GLP & Validation****Time: 10:30 AM To 1:30 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) Explain the types of process validation. | 06 |
| | (b) Explain in detail manufacturing requirements for solid dosage form. | 05 |
| | (c) Explain in detail Good distribution Practice. | 05 |
| Q.2 | (a) Write a short note on Quality audit. | 06 |
| | (b) Explain batch release document for finished products. | 05 |
| | (c) Explain various types of Recall. Explain Various GMP guidelines for recall related Procedures. | 05 |
| Q.3 | (a) Explain GMP guidelines for Packaging and labeling operation. | 06 |
| | (b) Explain roles and responsibilities of QA and QC in pharmaceutical industries. | 05 |
| | (c) Write a note on responsibilities of personnel in pharmaceutical organization. | 05 |
| Q.4 | (a) Explain in detail SOP for Compression and Cleaning operations in pharmaceutical industries. | 06 |
| | (b) Explain the process of clean in place and sterilize in place techniques. | 05 |
| | (c) Give a note on GMP guidelines for selection of vendors of raw materials. | 05 |
| Q.5 | (a) Explain Various Parameters for analytical method validation. | 06 |
| | (b) Write a short note on GLP. | 05 |
| | (c) Give brief account on Master Formula record. | 05 |
| Q. 6 | (a) Explain in detail Computer System Validation. | 06 |
| | (b) Write a note any two | 10 |
| | 1. Parenteral process validation | |
| | 2. Cleaning validation | |
| | 3. Liquid oral dosage forms process validation. | |
| Q.7 | (a) Write short notes (any two) | 16 |
| | 1. Validation of HPLC. | |
| | 2. Validation of dissolution test apparatus. | |
| | 3. Validation of UV-Visible spectroscopy. | |
