

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014

Subject Code: 1921502

Date: 31-05-2014

Subject Name: GMP, GLP and Validation

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.**

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|-------------|-----|---|-----------|
| Q.1 | (a) | Explain the importance and role of Quality Assurance in Pharma industry. | 06 |
| | (b) | Explain the purchase specification and vendor selection of raw materials. | 05 |
| | (c) | Define Quality audit. Classify and explain quality audit Pharmaceutical industry. | 05 |
| Q.2 | (a) | Explain the guidelines regarding organizational and personnel in Pharmaceutical industry. | 06 |
| | (b) | Explain the waste and scrap disposal procedure in Pharmaceutical industry. | 05 |
| | (c) | Short note on cleaning validation. | 05 |
| Q.3 | (a) | Define and classify recall of pharmaceutical product. Explain recall procedure of Pharmaceutical product in detail. | 06 |
| | (b) | Short note on Good Warehousing Practice. | 05 |
| | (c) | Define process validation and explain its types in detail. | 05 |
| Q.4 | (a) | Shortnote on good laboratory practice. | 06 |
| | (b) | Explain different types of Qualification and Maintenance of equipment. | 05 |
| | (c) | Explain the calibration of HPLC. | 05 |
| Q.5 | (a) | Explain process validation of coated tablets. | 06 |
| | (b) | Explain the specification regarding packaging and labeling control. | 05 |
| | (c) | Write down the SOP of coating and sterilization operation. | 05 |
| Q. 6 | (a) | Define calibration, validation and verification. Explain each term with example | 06 |
| | (b) | Write a note sampling criteria in Pharmaceutical industry. | 05 |
| | (c) | Write a note on Good Distribution Practice. | |
| Q.7 | | Write short notes (any two) | 16 |
| | | 1. Computer system validation. | |
| | | 2. Validation master plan | |
| | | 3. Calibration of UV-Visible spectroscopy. | |
