

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1921502

Date: 26-12-2014

Subject Name: GMP, GLP and Validation

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) | Explain the difference between quality assurance and quality control. | 06 |
| | (b) | Discuss the responsibilities of personnel and facilities to be provided to them. | 05 |
| | (c) | Who are vendors? How are raw materials stored and issued? | 05 |
| Q.2 | (a) | Discuss the guidelines for purchase, use and maintenance of equipments. | 06 |
| | (b) | Write the in-process controls required in manufacture of solid dosage forms. | 05 |
| | (c) | Discuss the considerations in selection of premises for pharmaceutical manufacturing unit. | 05 |
| Q.3 | (a) | What is line clearance? Describe the GMP guidelines followed for packaging and labeling operations. | 06 |
| | (b) | Describe the different functions of quality control department. | 05 |
| | (c) | Write a brief note on quality audits. | 05 |
| Q.4 | (a) | What are complaints? How are they handled? What records are maintained regarding complaints? | 06 |
| | (b) | Discuss the responsibilities of QA unit as per Good Laboratory Practices. | 05 |
| | (c) | Write a note on Good Warehousing Practice. | 05 |
| Q.5 | (a) | Define validation. Discuss its advantages. | 06 |
| | (b) | Describe the content of validation master plan. | 05 |
| | (c) | Differentiate between retrospective and prospective process validation. | 05 |
| Q. 6 | (a) | Describe the validation of tablet manufacturing process. | 08 |
| | (b) | Explain the important elements in cleaning validation. | 08 |
| Q.7 | (a) | Describe the different parameters of analytical method validation. | 08 |
| | (b) | Why should computer systems be validated? Explain the principles of computer system validation. | 08 |
