

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-I-EXAMINATION – JULY 2012

Subject code: 910204

Date: 07/07/2012

Subject Name: Good Manufacturing Practices and Good Laboratory Practices

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) | Write a note on vendor selection and certification. | 06 |
| | (b) | Discuss the general guideline for personnel selection, training and hygiene. | 05 |
| | (c) | Describe the maintenance of sterile area. | 05 |
| Q.2 | (a) | Define SOPs. What are objectives of writing SOPs | 06 |
| | (b) | Write an SOP for any one equipment used in sterile area. | 05 |
| | (c) | Describe the factors affecting location and construction of pharmaceutical industry. | 05 |
| Q.3 | (a) | Enlist the types of documents made in quality assurance department of pharmaceutical industry. What is specification and what information's it contains? | 06 |
| | (b) | Give the importance of documentation control in industry | 05 |
| | (c) | Give a standard format of master formula record. | 05 |
| Q.4 | (a) | Write a note on Quality audit and self inspection in pharmaceutical industry. | 06 |
| | (b) | What are service facility available in pharmaceutical industry. | 05 |
| | (c) | Write a note on WHO certification scheme. | 05 |
| Q.5 | (a) | Define GLP and OECD. Explain the key points in GLP. | 06 |
| | (b) | What is packing line clearance and reconciliation of label. | 05 |
| | (c) | What is quality control? Explain importance of quality control in pharma industry. | 05 |
| Q. 6 | (a) | Write a note on sampling plan. | 06 |
| | (b) | How disposal of waste is carried out in pharmaceutical industry. | 05 |
| | (c) | Give a format of Batch Manufacturing Record for manufacture of Hard Gelatin Capsule. | 05 |
| Q. 7 | (a) | What is IPQC? Explain IPQC test for tablet manufacture. | 06 |
| | (b) | Enlist the commonly used equipments in quality control dept. Explain any one equipment. | 05 |
| | (c) | Describe the control of contamination. | 05 |
