

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER 2013

Subject Code: 910204

Date: 26-12-2013

Subject Name: Good Manufacturing and Good Laboratory Practice

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) Describe Good Laboratory Practices guideline for drug testing laboratory in India. | 06 |
| | (b) Describe the basic elements of quality management:
I. Quality Assurance
II. GMP | 05 |
| | (c) Write a brief account on Waste disposal procedure with records. | 05 |
| Q.2 | (a) Define Recall strategy, Discuss recall strategy with its elements; Discuss the various reasons of recall. | 06 |
| | (b) Write short note on Quality Audit | 05 |
| | (c) Describe the advantages and disadvantages plastic containers with that of glass container. Discuss tests carried out on plastic containers. | 05 |
| Q.3 | (a) What are SOPs? Give objectives of SOP. Enumerate the topics of SOP. Describe the general format for SOP. | 06 |
| | (b) What are complains? Discuss types, handling of complains with general format of record. | 05 |
| | (c) What is importance of label control in pharmacy? What are statutory labeling requirements? | 05 |
| Q.4 | (a) Describe the raw material specifications with suitable examples. | 06 |
| | (b) What is the aim of warehousing? Describe good warehousing practices for raw material and finished product. | 05 |
| | (c) Write a note on Testing and release of finished product. | 05 |
| Q.5 | (a) Describe the elements with significance of WHO certification scheme. | 06 |
| | (b) Write a note on selection and purchase specifications of equipments for manufacturing. | 05 |
| | (c) Discuss selection and purchase specifications of an equipments for manufacturing. | 05 |
| Q. 6 | (a) Describe the master formula record and batch manufacturing record in detail. | 06 |
| | (b) Describe in detailed general consideration for factory premises. | 05 |
| | (c) What are the sources of particulate contamination? Describe the in process quality controls for sterile dosage forms briefly. | 05 |
| Q.7 | (a) Write brief note on Selection of vendor | 06 |
| | (b) Discuss sampling plans and sampling procedure for raw material. | 05 |
| | (c) Describe responsibilities and training guideline for personnel. | 05 |
