

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER • 2015****Subject Code: 910204****Date: 25-05-2015****Subject Name: Good Manufacturing and Good Laboratory Practice****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) | How market complains regarding pharmaceutical formulation handled? Explain the procedures for recalling a product. | 06 |
| | (b) | What is the requirement of quality review and quality audit of finished goods? Classify Quality audits. | 05 |
| | (c) | What is acceptable method for detecting residues of contaminants in evaluating cleansing validation? | 05 |
| Q.2 | (a) | Enlist pharmaceutical waste? Describe disposal procedures and the records to be kept for Biological waste. | 06 |
| | (b) | Describe the general guidelines to be observed for labeling and packaging of finished product? | 05 |
| | (c) | What are cGMP guidelines for recruitment of technical staff in pharmaceutical manufacturing area? | 05 |
| Q.3 | (a) | Enlist SOP for Q.C. laboratory. Give the name of routine control instruments and reagents used in Quality Control Laboratory. | 06 |
| | (b) | Explain briefly the important elements of the WHO Certification scheme. | 05 |
| | (c) | Enumerate the tests carried out on plastic packaging materials. | 05 |
| Q.4 | (a) | Discuss design and maintenance of warehouse of a pharmaceutical company. | 06 |
| | (b) | What are GMP guidelines for testing of drug product containers and closures? | 05 |
| | (c) | Write a note on Vendor Certification. | 05 |
| Q.5 | (a) | Outline GLP guideline for animal house facility and animal care in a non-clinical testing laboratory. | 06 |
| | (b) | Write note on phases of equipment qualification. | 05 |
| | (c) | What are the guidelines given regarding use of automatic and electronic equipment? | 05 |
| Q. 6 | (a) | Describe briefly a good sampling procedure for sampling of starting materials. | 06 |
| | (b) | What are reserve samples? Discuss briefly its significance and norms. | 05 |
| | (c) | Describe the in-process quality checks performed for sterile dosage forms. | 05 |
| Q.7 | (a) | Give the regulatory guidelines for reprocessing of materials. | 06 |
| | (b) | Describe the key elements of a master manufacturing record. | 05 |
| | (c) | Explain in brief the IPQC parameters observed during the production of Controlled release Tablet. | 05 |
