

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm - SEMESTER I • EXAMINATION – WINTER 2016

Subject Code: 910204**Date: 04/01/2017****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) Enumerate different GMP guidelines for Drug Substance and Drug product. | 06 |
| | (b) Enlist various sections of warehouse and Good warehouse practices. | 05 |
| | (c) Write a note on self-inspection and quality audit. | 05 |
| Q.2 | (a) Write a note on complaint and recall of goods. | 06 |
| | (b) What is importance of Line Clearing and describe how it is practiced during Production and packing process? | 05 |
| | (c) Describe briefly a good sampling procedure for sampling of starting materials | 05 |
| Q.3 | (a) Write a note on WHO Certification Scheme | 06 |
| | (b) What are complains? Discuss types, handling of complains with general format of record. | 05 |
| | (c) Write in short about raw material purchase specification, vender selection and maintenance of store of raw material. | 05 |
| Q.4 | (a) Describe responsibilities and training guideline for personnel. | 06 |
| | (b) Describe equipment maintenance and cleaning guidelines according to GMP. | 05 |
| | (c) Write in short about GLP. | 05 |
| Q.5 | (a) What are Quality audits? Classify their various types. Describe the purpose of carrying out Internal audits. | 06 |
| | (b) What is IPQC? Explain IPQC test for tablet manufacture. | 05 |
| | (c) Explain plant layout and construction with reference to parental dosage form manufacturing. | 05 |
| Q. 6 | (a) Write note on testing of packaging material | 06 |
| | (b) Define Quality Assurance, GMP, GLP and explain their interrelationship | 05 |
| | (c) Define Calibration, Qualification, and Validation & Verification. Illustrate these terms referring to any one laboratory instrument | 05 |
| Q.7 | (a) What are standard operating procedures? What are the factors that must be considered while writing a SOP? | 06 |
| | (b) Write an account of Good Distribution Practices | 05 |
| | (c) What are the important factors considered while selecting and purchasing an equipment for manufacturing? | 05 |
