

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm - SEMESTER-II • EXAMINATION – SUMMER 2017

Subject Code: 2920207**Date: 31/05/2017****Subject Name: Quality Control & Quality Assurance****Time: 10:30 AM to 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 importance, principles and regulations of good distribution Practices. | 06 |
| | (b) Write a detailed note on Risk management | 05 |
| | (c) Describe the key components of master formula record. | 05 |
| Q.2 | (a) What is quality audit? Give the objectives of quality audit and benefits of GMP audit. | 06 |
| | (b) Write a note on master formula record OR batch formula record. | 05 |
| | (c) Give importance of waste and scrap disposal. Explain methods for biomedical waste. | 05 |
| Q.3 | (a) What are standard operating procedures? What are the factors must be considered while writing SOP. | 06 |
| | (b) Explain waste disposal procedures for pharmaceutical industry. | 05 |
| | (c) What are various ISO standards? Enlist them with their specific purpose. | 05 |
| Q.4 | (a) What are the personal qualifications required in an organization as per GMI? Give a neat and clean diagram of training and development cycle. | 06 |
| | (b) Discuss subpart D (equipment) as per cGMP. | 05 |
| | (c) Why it is important to do vendor qualification and certification? | 05 |
| Q.5 | (a) Describe the data to be submitted to the regulatory authority while applying the permission to conduct clinical trials in India. | 06 |
| | (b) Discuss the different tests used to check quality of glass used as a container in Pharmaceutical Product. | 05 |
| | (c) What is CTD? How it is useful in regulation of Pharmaceutical Products? | 05 |
| Q. 6 | (a) Explain in detail the regulatory procedure for the application of NDA. | 06 |
| | (b) Write a note on Air handling systems for sterile product as per GMP | 05 |
| | (c) Discuss in detail the procedure for obtaining patent in India | 05 |
| Q.7 | (a) What are the responsibilities of Production department of Pharm Industry? | 06 |
| | (b) Mention important verification steps for QA officer during packaging/labeling of finished product. | 05 |
| | (c) Discuss about stability testing of API as per ICH guideline. | 05 |
