

GUJARAT TECHNOLOGICAL UNIVERSITY
B. Pharm – SEMESTER VII • EXAMINATION – WINTER-2017

Subject Code: 2270015

Date: 16-11-2017

Subject Name: Quality by Design (QbD) and Process Analytical Technology (PAT)

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) | Explain requirement of QbD. Discuss the various elements of QbD. | 06 |
| | (b) | Give the full name of the following terminology: 1.QTPP 2. CMA 3. CQA 4. CPP 5. RLD. | 05 |
| | (c) | Give significance of design of experiments and risk assessment in pharmaceutical product development. | 05 |
| Q.2 | (a) | Enlist the optimization techniques and explain any one. | 06 |
| | (b) | Describe in detail Question Based Review (QbR). | 05 |
| | (c) | Explain in brief CTD. | 05 |
| Q.3 | (a) | Explain what is quality? Write about relevance of quality with respect to pharmaceuticals. | 06 |
| | (b) | Describe in detail Principles and Scope of Quality Risk Management. | 05 |
| | (c) | Discuss in detail general qualities of risk management process. | 05 |
| Q.4 | (a) | Describe in detail Management Responsibilities for Pharmaceutical Quality Management . | 06 |
| | (b) | Explain briefly Continual Improvement of Process Performance And Product Quality. | 05 |
| | (c) | Give the full name of HACCP and FMEA and explain briefly HACCP. | 05 |
| Q.5 | (a) | Explain detail case study of QbD for any one immediate release dosage forms. | 06 |
| | (b) | Describe in detail QbD for vaginal dosage forms considering manufacturing process variables, raw materials and desired attributes. | 05 |
| | (c) | Explain about the Real time release approach. | 05 |
| Q. 6 | (a) | Discuss in detail Introduction, Scope, Background of PAT. | 06 |
| | (b) | Write a note on Tools and Framework of PAT. | 05 |
| | (c) | Explain briefly Risk-Based Approach and Integrated Systems Approach for PAT. | 05 |
| Q.7 | (a) | Explain in detail QbD for Topical dosage forms considering manufacturing process variables, raw materials and desired attributes. | 06 |
| | (b) | Discuss in details strategy for implementation of PAT. | 05 |
| | (c) | Write in detail case study of QbD for any one Modified release dosage forms. | 05 |
