

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- 7 EXAMINATION – WINTER -2019

Subject Code: 2270015**Date: 28-11-2019****Subject Name: Quality by Design (QbD) and Process Analytical Technology (PAT)****Time: 10:30AM TO 01:30PM****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) | Enlist PAT tools and Explain process control tool. | 06 |
| | (b) | Give brief review on ICH Q9. | 05 |
| | (c) | Give importance of DoE and risk assessment in formulation development. | 05 |
| Q.2 | (a) | Explain requirement of QbD. Discuss the various elements of QbD. | 06 |
| | (b) | Give your inputs to develop zero defect formulation based on quality point of view. | 05 |
| | (c) | Give the difference between Classical optimization and statistical design | 05 |
| Q.3 | (a) | Write about Current approaches to QbD. | 06 |
| | (b) | Write a short note on question based review (QbR). | 05 |
| | (c) | Explain briefly Continual Improvement of Process Performance And Product Quality. | 05 |
| Q.4 | (a) | Explain what is quality? Write about relevance of quality with respect to pharmaceuticals. | 06 |
| | (b) | Explain about the Real time release approach. | 05 |
| | (c) | How one can improve the quality of product in manufacturing area. | 05 |
| Q.5 | (a) | What is design of experiment? Give method and application of optimization of parameters in formulation with example. | 06 |
| | (b) | Explain in brief CTD. | 05 |
| | (c) | Discuss in details strategy for implementation of PAT. | 05 |
| Q. 6 | (a) | Write in detail case study of QbD for one Modified release dosage forms. | 06 |
| | (b) | Write a note on risk based approach and integrated system approach. | 05 |
| | (c) | Explain the Failure Mode Effects Analysis (FMEA) | 05 |
| Q.7 | (a) | Explain the Hazard Analysis and Critical Control Points (HACCP) | 06 |
| | (b) | Give the full name of the following terminology: 1.QTPP 2. CMA 3. CQA
4. CPP 5. RLD. | 05 |
| | (c) | Explain Yate's method for optimization with example. | 05 |
