

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM – SEMESTER – VII • EXAMINATION – WINTER – 2015

Subject Code: 2270015

Date: 16/12/2015

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

Time: 10.30 AM to 1.30 PM

Total Marks: 80

Instructions:

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1** (a) Explain the following terms: **06**
1) QTPP 2) CQA 3) FMEA 4) Design Space 5) RLD 6) CMA
- (b) Write a note on approach and limitation of QbD. **05**
- (c) Give importance of DoE and risk assessment in formulation development. **05**
- Q.2** (a) Define Quality. Write a note on relevance of quality with respect to pharmaceuticals. **06**
- (b) Write a note on scope and Principle of Risk Management **05**
- (c) Explain HACCP and FMEA in detail **05**
- Q.3** (a) Write a note on pharmaceutical development and explain CTD (Common Technical Document) **06**
- (b) Explain Concept of Optimization and Optimization Parameters required for development of sustained and controlled release formulation. **05**
- (c) What is design of experiment? Give method and application of optimization of parameters in formulation with example. **05**
- Q.4** (a) Write a note on management responsibility for Pharmaceutical Quality System. **06**
- (b) How one can improve the quality of product in manufacturing area. **05**
- (c) Give your inputs to develop zero defect formulation based on quality point of view. **05**
- Q.5** (a) How will you determine and minimize the risk assessed in formulation. **06**
- (b) Give general quality risk management process. **05**
- (c) Give the difference between Classical optimization and statistical design **05**
- Q. 6** (a) What is PAT? Give its scope and framework. **06**
- (b) Write a note on risk based approach and integrated system approach. **05**
- (c) How PAT is implemented, explain with example. **05**
- Q.7** (a) Give QbD of immediate release formulation with example. **06**
- (b) Write a short note on question based review (QbR). **05**
- (c) Give brief review on ICH Q9. **05**
