

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Ph. - SEMESTER– VII • EXAMINATION – WINTER-2018

Subject Code: 2270015

Date: 28/11/2018

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.**

- Q.1** (a) Discuss the Process performance and product quality monitoring system as an element of ICH Q10 Pharmaceutical Quality System. **06**
- (b) Draw the CTD triangle and Explain the Module 5 Clinical study reports. **05**
- (c) Write a note on HACCP (Hazard Analysis and Critical Control Points). **05**
- Q.2** (a) Define QbD. Discuss the elements of QbD. **06**
- (b) Write two primary principles of QRM and Draw the flow chart of typical Quality Risk Management Process. **05**
- (c) Write a note on PAT tools. **05**
- Q.3** (a) Explain the Ishikawa Diagram that used as a Risk Assessment Tool. **06**
- (b) Define PAT. Discuss scope and principle of PAT. **05**
- (c) Explain Yate's method for optimization with example. **05**
- Q.4** (a) Explain the terminology QTPP and CPP with suitable example with respect to QbD. **06**
- (b) What is Risk Priority Number? Explain with any Risk Assessment Example. **05**
- (c) Write the total number of experiments and treatment combination and interaction chart for 3² Factorial design. **05**
- Q.5** (a) Compare the Traditional and QbD approach for Pharmaceutical product supply. **06**
- (b) Explain with example 1) CQA 2) CMA **05**
- (c) Write about need of QbD for Pharma sector. **05**
- Q. 6** (a) Discuss challenges for implementation of QbD. **06**
- (b) Explain the Real Time Release Study of PAT. **05**
- (c) Explain the mapping of CMA and CPP to CQAs with example. **05**
- Q.7** (a) Explain the CTD module 3 Quality in detail. **06**
- (b) Explain the Design Space. **05**
- (c) Explain the control strategy approach for Quality product. **05**
