Seat No.: _____ Enrolment No. _____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**B.PHARM. - SEMESTER– VII • EXAMINATION – SUMMER-2016**

**Subject Code: 2270015 Date: 13/05/2016**

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

**Time: 2:30 PM to 5:30 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)** | Define the following terminology.<br>1) Quality by Design (QbD)<br>2) Process Analytical Technology (PAT)<br>3) Design Space | **06** |
| | **(b)** | Enlist and explain the elements of QbD. | **05** |
| | **(c)** | Write Classification of optimization techniques and explain any one. | **05** |
| **Q.2** | **(a)** | Enlist PAT tools and Explain process control tool. | **06** |
| | **(b)** | Draw a flow chart of quality risk management process. | **05** |
| | **(c)** | Explain the Control strategy approach for Quality Product. | **05** |
| **Q.3** | **(a)** | Enlist the different parts of CTD. Explain any one in detail. | **06** |
| | **(b)** | Enlist and explain in brief the elements of QbD. | **05** |
| | **(c)** | Explain in brief Risk Base Approach and Integrated System Approach. | **05** |
| **Q.4** | **(a)** | Explain the following<br>1) QTPP (Quality Target Product Profile),<br>2) CQA (Critical Quality Attributes)<br>3) CPP (Critical Process Parameter) | **06** |
| | **(b)** | Write about Current approaches to QbD. | **05** |
| | **(c)** | Draw a process map for Immediate Release Dosage Form by QbD. | **05** |
| **Q.5** | **(a)** | Compare the minimal requirements and enhanced approaches by QbD to pharmaceutical development. | **06** |
| | **(b)** | Explain the Failure Mode Effects Analysis (FMEA) | **05** |
| | **(c)** | Explain the following with Pharmaceutical examples | **05** |
| **Q. 6** | **(a)** | Write about Quality target product profile with respect to Modified release dosage form. | **06** |
| | **(b)** | Write about Scope and principles of PAT. | **05** |
| | **(c)** | Explain the Hazard Analysis and Critical Control Points (HACCP) | **05** |
| **Q.7** | **(a)** | Explain scope, principle and overview of Quality Risk Management. | **06** |
| | **(b)** | Explain Yate's method for optimization with example. | **05** |
| | **(c)** | Explain about the Real time release approach. | **05** |

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