Seat No.: _____ Enrolment No. _____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**B.Pharm- SEMESTER–VII • EXAMINATION – WINTER -2020**

**Subject Code: 2270015** **Date: 16/01/2021**

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

**Time: 10:30AM To 12:30PM** **Total Marks: 54**

**Instructions:**

1. **Attempt any THREE questions from Q-1 to Q-6.**
2. **Q.7 is compulsory to attempt.**
3. **Make suitable assumptions wherever necessary.**
4. **Figures to the right indicate full marks.**

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|---|---|---|---|
| **Q.1** | **(a)** | What do you mean by QbD. Discuss its advantages and limitations. | **06** |
| | **(b)** | Explain in detail various elements of QbD. | **05** |
| | **(c)** | Write a note on "QTPP" | **05** |
| **Q.2** | **(a)** | Classify the optimization techniques and explain any one. | **06** |
| | **(b)** | List out the different parts of CTD. Explain any one in detail. | **05** |
| | **(c)** | Discuss in detail about Question Based Review (QbR). | **05** |
| **Q.3** | **(a)** | Discuss in detail about concept of optimization and optimization parameters with suitable example. | **06** |
| | **(b)** | Give the full name of FMEA and explain it in detail. | **05** |
| | **(c)** | Discuss in brief about "Statistical Designs" | **05** |
| **Q.4** | **(a)** | What is Quality? Write about scope and principles of Quality Risk Management | **06** |
| | **(b)** | Write a short note on Hazard Analysis and Critical Control Points (HACCP) | **05** |
| | **(c)** | Give brief note on Yate's method for optimization with an example. | **05** |
| **Q.5** | **(a)** | Write the detailed case study of QbD for any one Immediate release dosage forms | **06** |
| | **(b)** | Explain in detail Total Quality Management. | **05** |
| | **(c)** | Discuss in brief about continual Improvement of the Pharmaceutical Quality System. | **05** |
| **Q. 6** | **(a)** | Explain the QbD for oral unit dosage form dosage forms considering manufacturing process variables, raw materials and desired attributes. | **06** |
| | **(b)** | Discuss in detail case study of QbD for any one Modified release dosage forms. | **05** |
| | **(c)** | Explain in brief with respect to PAT (1) Risk based approach (2) Integrated system approach. | **05** |
| **Q.7** | **(a)** | Give the full name of PAT. Write about its background and scope in detail. | **06** |
| | | **OR** | |
| | **(a)** | Discuss the process control tool for PAT. | **06** |
| | | **OR** | |
| | **(a)** | How PAT is implemented. Explain it with suitable example. | **06** |

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