Seat No.: _____ Enrolment No. _____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**B.PHARM - SEMESTER–8 EXAMINATION – WINTER -2023**

**Subject Code: BP814TT Date: 06/12/2023**

**Subject Name: Pharmaceutical Product Development**

**Time:02.30 p.m. to 5.30 p.m. 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)** | Discuss in brief about process of Pharmaceutical Product development. | **06** |
| | **(b)** | Describe quality control tests of semi-solid dosage forms. | **05** |
| | **(c)** | Enumerate excipients used for parenteral dosage form. Explain preservatives in detail. | **05** |
| **Q.2** | **(a)** | Discuss ideal requirements of excipients used for Aerosol. Explain in brief about Propellant. | **06** |
| | **(b)** | Enumerate different types of solublizers with suitable examples. | **05** |
| | **(c)** | Describe objectives of coating of dosage form. Explain enteric coating materials in details. | **05** |
| **Q.3** | **(a)** | Discuss applications factorial design in optimization of a pharmaceutical formulation. | **06** |
| | **(b)** | Classify types of excients used in tablet. Explain Diluents and Binder. | **05** |
| | **(c)** | Write a note on stability assessment of capsule dosage form. | **05** |
| **Q.4** | **(a)** | Describe Regulatory requirements for selection of packaging materials. | **06** |
| | **(b)** | Explain in brief about excipients used for cream and ointment. | **05** |
| | **(c)** | Explain the ICH guidelines related to stability assessment of a dosage form. | **05** |
| **Q.5** | **(a)** | What is QbD? Describe advantages and challenges of QbD approach in product development. | **06** |
| | **(b)** | Describe applications of polyethylene glycols and Sorbitol's in pharmaceutical dosage forms. | **05** |
| | **(c)** | Write a note on directly compressible excipients. | **05** |
| **Q. 6** | **(a)** | Write a note simplex lattice design. | **06** |
| | **(b)** | What is IPQC? Explain its importance with suitable example of a dosage form. | **05** |
| | **(c)** | Write a note on Non-ionic surfactant and their applications. | **05** |
| **Q.7** | **(a)** | Define Preformulation Studies. Discuss objectives and regulations related to preformulation. | **06** |
| | **(b)** | Discuss in detail about various excipients used in the formulation of NDDS. | **05** |
| | **(c)** | Enumerate different types of packaging materials. Discuss glass as a packaging material. | **05** |

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