

GUJARAT TECHNOLOGICAL UNIVERSITY
B. Pharm – SEMESTER –VIII EXAMINATION – SUMMER -2022

Subject Code:BP814TT**Date:04/06/2022****Subject Name: Pharmaceutical Product Development****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.

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| Q.1 | (a) | What is Cyclodextrin? Give its applications in pharmaceutical product development | 06 |
| | (b) | Define Solvents. How solubilizers play important role in dosage form design? | 05 |
| | (c) | Explain the ICH guidelines related to stability assessment of a dosage form. | 05 |
| Q.2 | (a) | Describe the mechanism of action for different suspending and emulsifying agents with suitable examples. | 06 |
| | (b) | Explain in detail - quality control testing parameters of Tablets. | 05 |
| | (c) | Write a note on - excipients in parenteral and aerosols products. | 05 |
| Q.3 | (a) | Discuss selection and application of excipients for controlled drug delivery. | 06 |
| | (b) | How selection of coating materials play crucial role in release pattern of the dosage form? | 05 |
| | (c) | Write a note Polyethylene glycols as solubility enhancer for poorly soluble drugs. | 05 |
| Q.4 | (a) | What is IPQC? Explain its importance with suitable example of a dosage form. | 06 |
| | (b) | Explain role of factorial designs in optimization of a pharmaceutical formulation. | 05 |
| | (c) | What is QbD? Give its application in pharmaceutical product development. | 05 |
| Q.5 | (a) | Write a note on container closure system for semi-solid dosage forms. | 06 |
| | (b) | Describe various quality control testing of packaging materials for pharmaceutical products. | 05 |
| | (c) | What are the different selection criteria for glass- as packaging material for injectable products? | 05 |
| Q. 6 | (a) | Explain plackett and burman screening design with suitable examples. | 06 |
| | (b) | Give application of simplex lattice design with special reference to mouth dissolving dosage form. | 05 |
| | (c) | Write a note on excipients used in preparation of capsules. | 05 |
| Q.7 | (a) | Describe role of various excipients in semi-solid dosage form development. | 06 |
| | (b) | What are directly compressible vehicles? Give its applications. | 05 |
| | (c) | What is a mixture design? Explain with suitable example in detail. | 05 |
