

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.PHARM – SEMESTER – VIII EXAMINATION – WINTER-2025**

**Subject Code: BP814TT****Date:17-11-2025****Subject Name: Pharmaceutical Product Development****Time: 02:30 PM TO 05:30 PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1** (a) What are the critical stages in the pharmaceutical product development process? **06**  
(b) Write a note on the different risk assessment tools. **05**  
(c) Explain the ICH guidelines related to stability assessment of a dosage form **05**
- Q.2** (a) How screening designs and optimization designs differ? Explain the role of Plackett and Burman designs in pharmaceutical product development. **06**  
(b) What is a mixture design? Explain its application **05**  
(c) What is QbD? Explain the various elements of QbD. **05**
- Q.3** (a) Explain the role of Polyethylene Glycol and Sorbitol in Pharmaceutical formulation. **06**  
(b) Discuss the role of cyclodextrins in the development of pharmaceutical products. **05**  
(c) Describe non-ionic surfactants and their role in various pharmaceutical products. **05**
- Q.4** (a) Explain the enteric and non-enteric excipients used for tablet coating. **06**  
(b) Explain the excipients used in preparation of pharmaceutical aerosols. **05**  
(c) Discuss the criteria for the selection of excipient used for parenteral product development. **05**
- Q.5** (a) Discuss the advantages and disadvantages and selection criteria for using glass as a packaging material. **06**  
(b) What factors should be considered when selecting a packaging material or system for a product? **05**  
(c) Explain the formulation excipients of soft gelatin capsule **05**
- Q.6** (a) Write a note on mechanism of action and common binders and disintegrants used in tablet formulation. **06**  
(b) Write a detailed note on diluents used in tablet formulation. **05**  
(c) Write a note on excipients used in formulation of parenteral suspensions. **05**
- Q.7** (a) Explain factorial design with suitable example. **06**  
(b) Explain in detail the different excipients use for formulation of NDDS. **05**  
(c) Write a note on stability assessment of capsule dosage form. **05**

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