

**GUJARAT TECHNOLOGICAL UNIVERSITY****B.PHARM - SEMESTER- 8 EXAMINATION – SUMMER-2024****Subject Code:BP814TT****Date: 03/05/2024****Subject Name: Pharmaceutical Product Development****Time: 10.30 a.m. to 1.30 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.

- Q.1** (a) Describe Pharmaceutical Product development process with flow chart. **06**  
(b) Explain various phases of Clinical trial. **05**  
(c) Describe the accelerated stability testing method. **05**
- Q.2** (a) What is Cyclodextrin? Give its applications in pharmaceutical product Development. **06**  
(b) Discuss quality control test of capsule dosage form. **05**  
(c) Write note Polyethylene glycols as solubility enhancer for poorly soluble drugs. **05**
- Q.3** (a) Explain the co-process method for direct compressible excipients. **06**  
(b) Explain Glidant, Lubricants and Anti-adherents with example. **05**  
(c) Explain the sugar-coating process. **05**
- Q.4** (a) Explain Enteric and Non Enteric coating excipients. **06**  
(b) Enumerate ideal requirements of excipients used for Aerosol. Discuss about Propellant. **05**  
(c) Explain in brief about ointment bases. **05**
- Q.5** (a) Describe criteria for selection of excipients for parenteral dosage form. **06**  
(b) Explain advantages and disadvantages of Direct compression process for tablets. **05**  
(c) Explain the defects and their remedies for tablet coating. **05**
- Q. 6** (a) Explain Plackett and Burman screening design with suitable examples. **06**  
(b) Explain characteristics, merit, demerits and application of factorial design **05**  
(c) Explain in details: Excipients use for formulation of NDDS. **05**
- Q.7** (a) Explain advantages, disadvantages and types of glass for packing. **06**  
(b) Explain different types of closure. **05**  
(c) Explain various elements of QbD. **05**

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