

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.PHARM - SEMESTER-VIII EXAMINATION – WINTER -2022**

**Subject Code:BP814TT****Date: 23/12/2022****Subject Name: Pharmaceutical Product Development****Time: 02:30PM TO 05:30PM****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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|------------|---|-----------|
| <b>Q.1</b> | (a) Describe Pharmaceutical Product development process with flow chart.  | <b>06</b> |
|            | (b) Classify types of solublizers. Discuss in detail about the different pharmaceutical solublizers available in market.          | <b>05</b> |
|            | (c) Write a note on stability assessment of semisolid dosage form.  | <b>05</b> |
| <b>Q.2</b> | (a) Discuss quality control test of capsule dosage form.  | <b>06</b> |
|            | (b) Explain in brief about excipients used for cream.   | <b>05</b> |
|            | (c) Write a note on Emulsifying agent.  | <b>05</b> |
| <b>Q.3</b> | (a) Enumerate different types of disintegrant. Discuss in brief about Superdisintegrant.  | <b>06</b> |
|            | (b) What is QbD? Describe advantages and challenges of QbD approach.  | <b>05</b> |
|            | (c) Enumerate different types of packaging materials. Discuss glass as a packaging material.                                      | <b>05</b> |
| <b>Q.4</b> | (a) Enumerate ideal requirements of excipients used for Aerosol. Discuss about Propellant.  | <b>06</b> |
|            | (b) Describe properties, types and applications of Cyclodextrins.   | <b>05</b> |
|            | (c) Discuss use and applications of factorial design in product development.  | <b>05</b> |
| <b>Q.5</b> | (a) Classify types of excipients used in tablet. Explain Diluents and Binder.   | <b>06</b> |
|            | (b) Discuss selection criteria and quality control test of plastic as a packaging material.                                       | <b>05</b> |
|            | (c) Write a note on Polyethylene glycols and Sorbitol's.  | <b>05</b> |
| <b>Q.6</b> | (a) Classify type of closures. Discuss quality control test of closures.  | <b>06</b> |
|            | (b) Write a note on Enteric and Non Enteric coating excipients.   | <b>05</b> |
|            | (c) Describe criteria for selection of excipients for parenteral dosage form.   | <b>05</b> |
| <b>Q.7</b> | (a) Describe objectives of optimization techniques in Product development. Explain various parameters of optimization techniques. | <b>06</b> |
|            | (b) Enlist directly compressible excipients. Explain any two in detail.   | <b>05</b> |
|            | (c) Write a note on excipients used for formulation of NDDS.  | <b>05</b> |

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