

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER– 8 EXAMINATION – WINTER -2024

Subject Code:BP814TT**Date: 26-11-2024****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.

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| Q.1 | (a) What do you understand by the term pre-formulation studies? Discuss different parameters of pre-formulation process. | 06 |
| | (b) Solid state characterization is an important criterion for product development process. Discuss. | 05 |
| | (c) How a dosage form selection is done for a particular drug? State it in terms of flowchart if possible. | 05 |
| Q.2 | (a) State the difference between solubility and dissolution. Explain BCS and which category of excipients are used in improvement of dissolution rate of an API. | 06 |
| | (b) Explain in general the various Quality Attributes of an API that needs consideration during pharmaceutical product development process. | 05 |
| | (c) Describe various analytical test parameters of solid oral dosage form that are performed during product development process. | 05 |
| Q.3 | (a) Which are the different types of stability testing studies and mention the storage conditions, time duration and frequency of sampling required to be done for each type? | 06 |
| | (b) What is the importance of stability studies? Elaborate various ICH guidelines for the stability study. | 05 |
| | (c) Give the types of chemical stability reactions and discuss any one in detail. | 05 |
| Q.4 | (a) Classify suspending agents and state its importance. Flocculated system is better than deflocculated suspension. Comment on the given statement and give examples of flocculating agents. | 06 |
| | (b) Explain types of ointment bases with its application and examples. | 05 |
| | (c) Write a note on formulation components of a emulsion dosage form. | 05 |
| Q.5 | (a) Describe the role of each class of excipients used in formulation of parenteral dosage form citing examples from each class. | 06 |
| | (b) How many types of tablet coating are there? How they are different from each other in terms of formulation components discuss? | 05 |
| | (c) Categorize the types of excipients used in formulation of TDDS giving example of each type and its use in TDDS. | 05 |
| Q.6 | (a) Define the following terms: (Any 3)
1. QbD. 2. DoE 3. FMEA 4. QTPP | 06 |
| | (b) Enlist different types of design methodologies available under DoE and state the difference between screening design and optimization design. | 05 |
| | (c) Discuss factorial design in detail with a suitable example. | 05 |
| Q.7 | (a) Classify pharmaceutical packaging system based on the materials used for their fabrication. Discuss each in brief. | 06 |
| | (b) Write a short note on anti-counterfeiting technologies used in pharmaceutical packaging system. | 05 |
| | (c) Enumerate advantages of blister pack and discuss its components. | 05 |