

**PARUL UNIVERSITY**  
**FACULTY OF PHARMACY**  
**B. Pharm., Summer 2023-24 Examination**

Semester: 8

Date: 20/05/2024

Subject Code: BP813ET

Time: 10:00am to 1:00pm

Subject Name: **Pharmaceutical Product Development**

Total Marks: 75

**Instructions:**

1. All questions are compulsory.
2. Figures to the right indicate full marks.
3. Make suitable assumptions wherever necessary.
4. Start new question on new page.

<b>Q.1</b>	<b>Objective type Questions (Answer all the questions( (2 Mark Each)</b>	<b>(20)</b>	<b>CO</b>	<b>PO</b>	<b>BT</b>
1.	Comment: Features of packaging material is important for stability.		5	1,4,8,9	2
2.	Define Preformulation Studies with its objectives.		1	1,4,6,11	1
3.	Discuss ideal requirements of excipients used for Aerosol.		3	1,4,6,11	2
4.	How solubilizers play important role in dosage form design?		2	1,3,6,7	4
5.	Classify the various coating materials with examples.		3	1,4,6,11	1
6.	Explain the different climatic zones in stability testing.		1	1,4,6,11	1
7.	What is full factorial design and fractional factorial design?		4	1,6,8,11	3
8.	Enumerate different types of glass material with its properties for the packaging.		5	1,4,8,9	4
9.	Define optimization. Enlist the optimization designs.		4	1,6,8,11	1
10.	Classify the Emulsifying agents with examples.		2	1,3,6,7	2
<b>Q.2</b>	<b>Long Answers (Answer 2 out of 3) (10 Mark Each)</b>	<b>(20)</b>			
1.	(a)What is IPQC? Explain its importance with suitable example of a dosage form.		1	1,4,6,8,11	3
	(b) Discuss applications of factorial design in optimization of a pharmaceutical formulation.		4		4
2.	(a) Give a detailed note on properties, types and applications of cyclodextrins.		2	1,3,6,7,4,8,9	1
	(b) Describe various quality control tests for glass containers.		5		4
3.	(a) Enumerate excipients used for parenteral dosage form. Explain preservatives in detail.		3	1,4,6,11	2
	(b) Explain the ICH guidelines related to stability assessment of a dosage form.		1		4
<b>Q.3</b>	<b>Short Answers (Answer 7 out of 9) (5 Mark each)</b>	<b>(35)</b>			
1.	Describe pharmaceutical product development process with flow chart.		1	1,4,6,11	1
2.	What are the elements of QbD and how can it be useful in pharmaceutical product development ?		4	1,6,8,11	3
3.	Enumerate different types of disintegrants. Discuss in brief about superdisintegrants.		3	1,4,6,11	1
4.	Discuss different types of packaging materials used for pharmaceutical packaging.		5	1,4,8,9	4
5.	Discuss the selection of packaging material for pharmaceutical products.		5	1,4,8,9	3
6.	Discuss the role of the suspending agents in the formulation of suspension		2	1,3,6,7	2
7.	Explain in brief about excipients used in cream formulations.		2	1,3,6,7	1
8.	Explain 2 <sup>2</sup> factorial design with example.		4	1,6,8,11	2
9	Write a note on excipients used for formulation of NDDS.		3	1,4,6,11	1