Seat No.:	Enrolment No.

GUJARAT TECHNOLOGICAL UNIVERSITY B. Pharm – SEMESTER –VIII EXAMINATION – SUMMER -2022

Subject Code:BP814TT Date:04/06/2022

Subject Name: Pharmaceutical Product Development

Time: 10:30am to 01:30pm 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 is Cyclodextrin? Give its applications in pharmaceutical product development	06
	(b) (c)	Define Solvents. How solubilizers play important role in dosage form design? Explain the ICH guidelines related to stability assessment of a dosage form.	05 05
Q.2	(a)	Describe the mechanism of action for different suspending and emulsifying agents with suitable examples.	06
	(b) (c)	Explain in detail - quality control testing parameters of Tablets. Write a note on - excipients in parenteral and aerosols products.	05 05
Q.3	(a) (b)	Discuss selection and application of excipients for controlled drug delivery. How selection of coating materials play crucial role in release pattern of the dosage form?	06 05
	(c)	Write a note Polyethylene glycols as solubility enhancer for poorly soluble drugs.	05
Q.4	(a) (b)	What is IPQC? Explain its importance with suitable example of a dosage form. Explain role of factorial designs in optimization of a pharmaceutical formulation.	06 05
	(c)	What is QbD? Give its application in pharmaceutical product development.	05
Q.5	(a) (b)	Write a note on container closure system for semi-solid dosage forms. Describe various quality control testing of packaging materials for pharmaceutical products.	06 05
	(c)	What are the different selection criteria for glass- as packaging material for injectable products?	05
Q. 6	(a) (b)	Explain plackett and burman screening design with suitable examples. Give application of simplex lattice design with special reference to mouth dissolving dosage form.	06 05
	(c)	Write a note on excipients used in preparation of capsules.	05
Q.7	(a) (b)	Describe role of various excipients in semi-solid dosage form development. What are directly compressible vehicles? Give its applications.	06 05
	(c)	What is a mixture design? Explain with suitable example in detail.	05
