Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– 8 EXAMINATION – SUMMER -2023

Subject Code: BP814TT Date: 30/06/2023

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)**	Define Quality by Design concept and explain its importance. How QbD is different from the conventional traditional approach?	**06**
	(b)	Discuss the basic fundamentals of design of experimentation	**05**
	(c)	Enlist different screening and optimization designs used in formulation development. Explain full factorial design giving a suitable example for 2 factor and 3 level.	**05**
Q.2	**(a)**	Discuss stability testing parameters for dosage forms tablets, capsules, emulsions, topical dosage form, metered dose inhalers and suppositories.	**06**
	(b)	Which are the primary evaluation parameters needed to be studied as a part of a pre-formulation study in a pharmaceutical product development process.	**05**
	(c)	What is the importance of solubility study in pharmaceutical product development process and how equilibrium solubility study is done?	**05**
Q.3	**(a)**	Define: PAT, Design Space and QTTP.	**06**
	(b)	Draw a flow chart describing formulation steps of any dosage form adopting the concept of quality by design.	**05**
	(c)	How many types of stability studies are there and what is the importance of performing it during formulation development process?	**05**
Q.4	**(a)**	Write a short note on plastics as a pharmaceutical packaging material.	**06**
	(b)	Write in detail about the regulatory considerations for development of a pharmaceutical pack.	**05**
	(c)	What should be the ideal content of a patient information leaflet and discuss it in order of its appearance?	**05**
Q.5	**(a)**	Explain different formulation ingredients needed for preparing tablet dosage form by wet granulation method and discuss each category in detail with example.	**06**
	(b)	Write a note on super-disintegrants.	**05**
	(c)	Which different parameters are evaluated of hard gelatin capsule shell during its development?	**05**
Q. 6	**(a)**	Discuss cyclodextrins and its application in product development	**06**
	(b)	Write a note on control release polymers used in pharmaceutical development process.	**05**
	(c)	Classify semi-solid excipients and write in brief about them with example	**05**
Q.7	**(a)**	What is CMA, CPP and CQA?	**06**
	(b)	Importance of pre-formulation study in pharmaceutical development process	**05**
	(c)	Write a note on placket-burman design.	**05**

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