Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

BPHARM – SEMESTER VII • EXAMINATION – WINTER • 2016

Subject code: 2270001 **Date: 17-11-2016**

Subject Name: Dosage Form Design - I

Time: 10:30 am - 01:30 pm **Total Marks: 70**

Instructions:

1. **Attempt all questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q-1

a.	Define Half life, Self life and Overage. Discus about international climatic zones as per ICH guideline	**06**
b.	Discuss Matrixing and Bracketing Techniques: Purpose and objective.	**05**
c.	Explain accelerated stability studies to find out shelf life with limitations as per ICH guidelines.	**05**

Q-2

a.	Define preformulation. Write a note on physicochemical properties related to solubility study in preformulation.	**06**
b.	Explain the role of polymorphism and crystallinity in Preformulation. Enlist the methods to identify polymorphism.	**05**
c.	What do you understand by prodrug? Give its applications for improving stability of drug.	**05**

Q-3

a.	Enlist various mechanisms of drug transport. Discus active transport in detail.	**06**
b.	Explain effect of pKa and pH on absorption parameter.	**05**
c.	Short note on kinetics of Plasma protein binding.	**05**

Q-4

a.	Writ full name BCS with its classification. Give its objective. Write factors affecting drug dissolution with respect to test apparatus.	**06**
b.	How the bioavailability of drug can be improved?	**05**
c.	Write a note on similarity factor and dissimilarity factor.	**05**

Q-5

a.	Define bioavailability and bioequivalence. Enlist methods of measurement of bioavailability. Discuss latin-square cross-over design.	**06**
b.	Enlist the chemical properties observed during preformulation study. Explain oxidation in detail	**05**
c.	Discuss criteria for waiver of in vivo bioavailability study with reference to drug product.	**05**

Q-6

a.	Write a note on pharmaceutical excipients used as tablet binder and granulating agent.	**06**
b.	Write a note on suspending agents and emulsifiers used in liquid formulations.	**05**
c.	What do you understand by adjuvants? How are they utilized in designing innovative dosage forms?	**05**

Q-7

a.	Discuss the effect of containers and closures on stability of pharmaceuticals.	**06**
b.	Enlist the theories of dissolution. Explain in detail Film Theory	**05**
c.	Volunteer selection for bioavailability studies is a critical issue. Discuss the statement with examples.	**05**

****