Seat No.:	Enrolment No.
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## 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 d	questions.

- 2. Make suitable assumptions wherever necessary.
- 3. Figures to the right indicate full marks.

Q-1 a. b. c.	Define Half life, Self life and Overage. Discus about international climatic zones as per ICH guideline Discuss Matrixing and Bracketing Techniques: Purpose and objective. Explain accelerated stability studies to find out shelf life with limitations as per ICH guidelines.	06 05 05
Q-2 a. b. c.	Define preformulation. Write a note on physicochemical properties related to solubility study in preformulation.  Explain the role of polymorphism and crystallinity in Preformulation. Enlist the methods to identify polymorphism.  What do you understand by prodrug? Give its applications for improving stability of drug.	06 05 05
Q-3 a. b. c.	Enlist various mechanisms of drug transport. Discus active transport in detail. Explain effect of pKa and pH on absorption parameter. Short note on kinetics of Plasma protein binding.	06 05 05
Q-4 a. b. c.	Writ full name BCS with its classification. Give its objective. Write factors affecting drug dissolution with respect to test apparatus.  How the bioavailability of drug can be improved?  Write a note on similarity factor and dissimilarity factor.	06 05 05
Q-5 a. b. c.	Define bioavailability and bioequivalence. Enlist methods of measurement of bioavailability. Discuss latin-square cross-over design. Enlist the chemical properties observed during preformulation study. Explain oxidation in detail Discuss criteria for waiver of in vivo bioavailability study with reference to drug product.	06 05 05
Q-6 a. b. c.	Write a note on pharmaceutical excipients used as tablet binder and granulating agent. Write a note on suspending agents and emulsifiers used in liquid formulations. What do you understand by adjuvants? How are they utilized in designing innovative dosage forms?	06 05 05
Q-7 a. b. c.	Discuss the effect of containers and closures on stability of pharmaceuticals. Enlist the theories of dissolution. Explain in detail Film Theory Volunteer selection for bioavailability studies is a critical issue. Discuss the statement with examples.	06 05 05

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