

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B. Pharm. - SEMESTER-7 • EXAMINATION – SUMMER -2018**

**Subject Code: 270001****Date: 19/5/2018****Subject Name: Dosage Form Design- I****Time: 02:30 PM TO 05:30 PM****Total Marks: 80**

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

- Q.1** (a) What is intrinsic solubility? How is it measured? **02**  
(b) What is partition coefficient? What is its significance in preformulation? **04**  
(c) What is photolysis? Describe the means to prevent photodegradation of drugs. **05**  
(d) What is pro-drug? Describe the prodrug design approach for drug targeting with examples. **05**
- Q.2** (a) What are disintegrants? Name four superdisintegrants? **02**  
(b) What are ointments? Describe the different types of suppository bases. **04**  
(c) Enumerate additives used in tablets. Discuss tablet binders. **05**  
(d) What is flavor? Describe flavors used in liquid formulations. **05**
- Q.3** (a) Define: Product Shelf Life and Mean Kinetic Temperature. **02**  
(b) What is formulation stability? Discuss the different climatic zones for stability testing. **04**  
(c) What are overages? How are they calculated? In which formulations are they allowed? **05**  
(d) Describe matrixing and bracketing in stability study. **05**
- Q.4** (a) Explain: Drug Disposition and Dosage Form Design. **02**  
(b) What is protein drug binding? Describe displacement drug interactions in protein binding. **04**  
(c) What is drug transport? Describe passive diffusion process for drug transport. **05**  
(d) Describe the pH Partition theory for drug absorption. **05**
- Q.5** (a) What is GFR? Which are the markers used to measure it? **02**  
(b) Describe Latin Square cross over design for bioequivalence study. **04**  
(c) What is suprabioavailability? Describe AUC, C<sub>max</sub> and T<sub>max</sub> as bioavailability measures. **05**  
(d) What is absolute and relative bioavailability? Calculate these values for capsule based on given data. Capsule (Dose-200 mg Oral, AUC-40); Solution (Dose-200 mg Oral, AUC-60) and Injection (Dose-100 mg IV bolus, AUC-100). **05**
- Q.6** (a) Explain: Biowaivers. **02**  
(b) What is BCS? What is its significance in dosage form design? **04**  
(c) What is biorelevant dissolution media? Name the USP dissolution apparatus with the use. **05**  
(d) What is dissolution efficiency? Describe dissolution data comparison based on f<sub>1</sub> and f<sub>2</sub>. **05**
- Q.7** (a) What is ICH? Describe the ICH guidelines for stability. **04**  
(b) What is BBB? Describe approaches used to target polar drugs to brain. **04**  
(c) Describe drug binding to HAS. **04**  
(d) What is sink condition? Describe methods to achieve *in vitro* sink condition. **04**

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