

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm. SEMESTER-I • EXAMINATION – SUMMER-2016****Subject Code: 910102****Date: 27/05/2016****Subject: Pharmaceutical Formulation, Development & Biopharmaceutics****Time: 10:30 AM to 1:30 PM****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 do you mean by preformulation. Give the brief note on importance of preformulation study. **06**
- (b) Discuss objective of stability study. Describe various instability in pharmaceutical formulation. **05**
- (c) Write a note on polymorphism. **05**
- Q.2** (a) Describe the physical factors that affect formulation of drug. **06**
- (b) Write a note on protein binding. **05**
- (c) Describe the method of Residual to determine K_a and K_e . **05**
- Q.3** (a) Describe the types of dissolution apparatus as accordance with the USP. **06**
- (b) Write a note on CACO 2 monolayers. **05**
- (c) Describe the preformulation studies of biotechnological derived products. **05**
- Q.4** (a) Discuss the criteria on the basis of which, the selection of dissolution media and related conditions are finalized. **06**
- (b) Discuss the applications of microcalorimetry in stability study. **05**
- (c) Discuss the formulation and evaluation of Herbal Shampoo. **05**
- Q.5** (a) A new antibiotic drug was given in a single intravenous bolus of 4 mg/kg to five healthy male adults ranging in age from 23 to 38 years (average weight 75 kg). The pharmacokinetics of the plasma drug concentration–time curve for this drug fits a one-compartment model. The equation of the curve that best fits the data is $C_p = 78e^{-0.46t}$
Determine the following (Assume units of microgram/ml for C_p and hr for t):
What is the $t_{1/2}$ and V_D . What is the plasma level and drug is left in the body after 4 hours. **06**
- (b) Explain: Total Clearance, Volume of distribution. **05**
- (c) Write a note on Photostability testing of pharmaceutical products. **05**
- Q. 6** (a) Write a note on transparent toothpaste. **06**
- (b) Explain the Physicochemical factors affecting the drug absorption. **05**
- (c) Write a note on “Drug-Excipient compatibility study” **05**
- Q.7** (a) Write a note on IVIVC. **08**
- (b) Enlist various techniques for solubility enhancement. Discuss any two in detail. **08**
