

UKA TARSADIA UNIVERSITY

Maliba Pharmacy College

M. Pharm. Pharmaceutics 1st Semester Internal Examination December 2013**040040102 Pharmaceutical Formulation, Development & Biopharmaceutics**

Time: 10:30 a.m. To 1:30 p.m.

Max. Marks: **70**

Date: 06/12/2013

Instructions:

- Attempt any **FIVE** questions.
- Each question carries **14** marks.
- Make suitable assumption whenever necessary.
- Figures to the right indicate full marks.

- Q. 1**
- A)** Define clearance, organ clearance and total clearance? Derive a relationship for the estimation of extraction ratio. Explain the significance of extraction ratio. **04**
- B)** Write a note on physiologic pharmacokinetic model. Enlist its advantages and disadvantages over compartment models. **04**
- C)** Discuss the objectives of performing BA/BE studies. **06**
- Q. 2**
- A)** What do you understand by compartment modeling? Why the compartments are termed 'open systems'? Discuss the practical relevance of mammillary and catenary models. **04**
- B)** What do you understand by volume of distribution (Vd)? Why is it termed 'apparent volume of distribution' rather than 'real volume of distribution'? Drugs X and Y, when administered intra-orally, have Vd of 10L and 200L, respectively. What does it signify in pharmacokinetic terms? **04**
- C)** Discuss the important pharmacokinetic and pharmacodynamic parameters which can be obtained from a typical plasma concentration-time profile. Assume that the formulation has been administered intra-orally. **06**
- Q. 3**
- A)** Discuss: Particle size reduction techniques for solubility improvement. **04**
- B)** Explain in detail: Solid Dispersion techniques for solubility improvement. **04**
- C)** Discuss the estimation of Ka by the method of residuals as applied to one compartment open model (extra-vascular administration) following first order absorption. **06**
- Q. 4**
- A)** What is the mechanism of solubilization. Why improvement in drug solubilization is necessary for formulation and development? **04**
- B)** Classify cosmetics, and discuss formulation and evaluation of vanishing cream. **04**
- C)** Write a detail note on Solubilization techniques by Chemical Modifications. **06**
- Q. 5**
- A)** Explain hydrolysis/solvolysis mode of degradation. **04**
- B)** Discuss objectives for carrying out stability studies of pharmaceutical products. **04**
- C)** Explain various potential adverse effects of instability in pharmaceutical products. **06**
- Q. 6**
- A)** Explain briefly factors affecting polymorphism. **04**
- B)** Enlist factors chemical affecting formulation with reference to preformulation study. **04**
- C)** Enlist factors affecting stability of pharmaceutical product. Describe and discuss effect of light and pH on stability of pharmaceutical product giving examples. **06**