

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM. - SEMESTER – I • EXAMINATION – WINTER 2012

Subject code: 910102

Date: 09/01/2013

Subject Name: Pharmaceutical Formulation Development & Biopharmaceutics

Time: 10.30 am - 01.30 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) A Pharmacist wants to develop a transdermal patch of hormone. What test should be carried out in order to ascertain drug-excipient incompatibility? Give outline and significance of each test. 06
- (b) What do you mean by intrinsic solubility? Enlist various solubilization techniques with their mechanisms. Discuss importance of β -cd utility number and derivation of it. 05
- (c) Describe the equipment related factors affecting results of dissolution testing. 05
- Q.2 (a) "Preformulation studies are limited to new drug molecules only"- Comment. Suggest different means to arrest hydrolysis of APIs. 06
- (b) "Bioavailability of poorly soluble APIs is challenge to formulation pharmacist" Discuss physical and chemical modifications of APIs and use of excipients to solve this issue. 05
- (c) Discuss the dissolution test for unconventional and novel dosage forms using biorelevant media. 05
- Q.3 (a) How the particle engineering influence the development of compacted APIs and its compressed dosage forms? Comment- Crystallization is inhibited by PVP. 06
- (b) Give an idea about BCS classification. Discuss the breakthrough technology and future prospects of solid-dispersion technology. 05
- (c) How will you compare dissolution profiles? Discuss the strategies regarding facilitation/Challenges to dissolution for poorly soluble drugs. 05
- Q.4 (a) What happens due to instability in Pharma-formulations? What are objectives of stability testing? Enumerate types of stability studies. 06
- (b) Enlist the factors affecting drug absorption. Write in details about the factors related to physiological conditions and formulation of dosage form. 05
- (c) Define Pharmacokinetics, pharmacodynamics and biopharmaceutics. How does basic pharmacokinetic parameters help in designing dosage form? 05
- Q.5 (a) What significant changes occurs due to accelerated testing? Discuss the methods to predict shelf-life from accelerated stability data. 06
- (b) What is the need for bioavailability- bioequivalence study? What molecules have greatest potential to bioavailability problem? Enlist the methods to assess BA. 05
- (c) What is the significance of measuring plasma drug concentration? Describe importance and type of pharmacokinetic model. 05
- Q.6 (a) What are effects of various environmental and processing factors on stability of formulation? What are regulatory status against environmental conditions for stability evaluations. 06
- (b) What is PAMPA? Compare it with CACO2. 05
- (c) A physician want to administer an anesthetic agent at a rate of 2mg/hr by IV infusion. The elimination rate constant is 0.1 hr^{-1} And the volume of distribution (one compartment) is 10L. What is the loading dose is recommended if doctor wants the drug level to reach 2mg/ml immediately. What is C_{ss} ? 05
- Q.7 (a) What is IVIVC? What are the criteria, objective and need for IVIVC? What are the levels for correlation? Why it fails for immediate release dosage forms? 06
- (b) What factors are affecting the development of predictable IVIVC? 05
- (c) Suggest evaluation of products containing herbal ingredients. Comment on recent trends covering phytopharmaceuticals' monographs in latest BP/USP/EP and IP 05
