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.**

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|---|---|---|---|
| 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) | " Bioavailibility 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 biorelavant 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, pharmacodynemics 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 metods 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 Css? | 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 |

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