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)	" 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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