Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2014

Subject Code: 910102 Date: 07-01-2015

Subject Name: Pharmaceutical Formulation, Development and 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)	Define preformulation. Discuss pharmaceutical factors influencing formulation of a drug.	**06**
	(b)	Write a note on Drug Excipient compatibility study.	**05**
	(c)	Discuss preformulation studies of Biotechnological products.	**05**
Q.2	(a)	Discuss basic concept and objectives of stability study.	**06**
	(b)	Explain effects of various chemical parameters on stability of dosage forms.	**05**
	(c)	Discuss the considerations of OVIs (Organic Volatile Impurities) in preformulation study.	**05**
Q.3	(a)	Discuss the importance of BCS in dosage form development.	**06**
	(b)	Write a note on selection of dissolution media and conditions for dissolution study.	**05**
	(c)	Discuss general regulatory requirements of stability testing.	**05**
Q.4	(a)	Define solubilization. Discuss various techniques for improvement of drug solubilization for development of dosage forms.	**06**
	(b)	What is intrinsic solubility? How it differs from dissolution? Discuss a method to determine intrinsic solubility of a drug.	**05**
	(c)	What is dissolution mimicking? Explain Bio-relevant media.	**05**
Q.5	(a)	Discuss factors affecting In-vivo In-vitro (IVIVC) correlation.	**06**
	(b)	Write a note on methods of establishing IVIVC.	**05**
	(c)	Define bioavailability and bioequivalence. Enumerate methods of measurement of bioavailability. Discuss briefly latin-square cross over design.	**05**
Q. 6	(a)	Define apparent volume of distribution, biological half life and total body clearance. Describe method to determine V_d of the new drug molecule.	**06**
	(b)	What is multicomponent model? Enumerate such multicompartment models and write a note on two compartment model.	**05**
	(c)	Write a note on methods of evaluation of shampoo.	**05**
Q. 7	(a)	Discuss different factors affecting drug absorption	**06**
	(b)	Discuss determination of bioavailability of drug using urinary excretion data.	**05**
	(c)	Write a note on formulation and evaluation of Herbal Toothpaste.	**05**

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