Seat N	o.:	GUJARAT TECHNOLOGICAL UNIVERSITY	
	N	M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2014	
Subje	ect Co	de: 910102 Date: 07-01-2015	
Subje	ect Na	me: Pharmaceutical Formulation, Development	
Т: с	. 10.2	and Biopharmaceutics	
	: 10:5 ctions:	0 am - 01:30 pm Total Marks: 80	
insti u		tempt any five questions.	
		ake suitable assumptions wherever necessary.	
	3. Fig	gures 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	05
	(c)	dissolution study. Discuss general regulatory requirements of stability testing.	05
	(•)	2 is case general regulatory requirements or statement, resuming.	02
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	05

models and write a note on two compartment model.

(c) Write a note on methods of evaluation of shampoo.

(a) Discuss different factors affecting drug absorption

(b) Discuss determination of bioavailability of drug using urinary excretion data.

(c) Write a note on formulation and evaluation of Herbal Toothpaste.

05
