Seat No.:	Enrolment No.
Sear NO	EULOHUEUL NO

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. - SEMESTER - I • EXAMINATION - SUMMER 2013

Subject Code: 910102		Code: 910102 Date: 15-05-2013	
Subj	ect]	Name: Pharmaceutical Formulation,	
		Development and Biopharmaceutics	
Time	e: 10	0.30 am - 01.30 pm Total Marks: 80	
Instr	uctio	ns:	
		Attempt any five questions.	
		Make suitable assumptions wherever necessary.	
	3.	Figures to the right indicate full marks.	
Q.1	(a)	IVIVC can be improved by making necessary changes in the dissolution media,	06
C	()	<i>in-vitro</i> dissolution set up and in the dosage form. Comment and discuss.	
	(b)	Discuss the pharmaceutical factors affecting preformulation.	05
	(c)	Explain: Total Clearance, Volume of distribution.	05
Q.2	(a)	What are OVIs. What are their sources. Discuss its classification based on risk	06
Q.2	(a)	assessment of residual solvent.	vv
	(b)	Describe the ICH guidelines for Photostability testing of new drug substance and	05
	` '	product.	
	(c)	Write a note on Protein Binding.	05
Q.3	(a)	Describe the dissolution apparatus for buccal tablets and transdermal patches.	06
Q.J	(b)	Elaborate the necessity of drug-excipient compatibility study with examples.	05
	(0)	Discuss how it is carried out.	
	(c)	Give the importance of BCS in dosage form development.	05
Q.4	(a)	Give the details of diffusion layer model with respect to theories of dissolution.	06
ų.T	(b)	Write a note on Biorelevant Media.	05
	(c)	Describe the stability aspects of the biotechnologically derived products.	05
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Q.5	(a)	Explain the meaning of the following terms related to stability: Accelerated	06
	(1-)	stability testing, Long term stability testing, Forced degradation stability testing.	05
	(b)	How crystallinity and polymorphism influences the dissolution of drug from the dosage form.	05
	(c)	What are the objectives of IVIVC. Describe various levels of IVIVC correlation.	05
	(0)	what are the objectives of ivive. Beschie various levels of ivive contention.	0.5
Q. 6	(a)	Enlist all techniques of dissolution enhancement and discuss any one in detail.	06
	(b)	* *	05
		this cell lines.	
	(c)	Enlist the physiological factor affecting drug absorption. Describe any two.	05
Q. 7	(a)	Discuss formulation and evaluation aspects of different types of shampoos.	06
~··	(b)	What is importance of measuring plasma drug concentration. Describe different	05
		types of Pharmacokinetics model.	
	(c)	Write note on application of Microcalorimeter in pharmacy.	05
