Seat No.: _____ **Enrolment No._____**

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph SEM-VII Examination-Nov/Dec.-2011

Subject code: 270001 **Date: 19/11/2011**

Subject Name: Dosage Form Design-I

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)	Explain wetting. How is it measured?	**02**
	(b)	Discuss the significance of particle size and shape in formulation.	**04**
	(c)	What is preformulation? What is the importance of polymorphs in preformulation?	**05**
	(d)	Explain mutual prodrugs. Describe the prodrug design for masking taste and odor of drugs.	**05**
Q.2	(a)	Name four FD & C approved colors used in formulations.	**02**
	(b)	Classify ointment bases. Describe water washable bases.	**04**
	(c)	Enumerate additives used in tablets. Discuss bulking agents.	**05**
	(d)	How suspending agents work? Describe suspending agents in liquid formulations.	**05**
Q.3	(a)	Define: Formulation stability and MKT.	**02**
	(b)	A drug in suspension (100mg/ mL) degrades by zero-order kinetics with a rate constant of 0.5 mg/mL hr. Calculate the shelf life of drug. How much drug will be left after 48 hr?	**04**
	(c)	What is accelerated stability testing? How can it be correlated with real time stability?	**05**
	(d)	What are overages? What is permissible limit? Describe calculation of overages.	**05**
Q.4	(a)	Explain: Biopharmaceutics and RDS.	**02**
	(b)	What is Vd? Describe displacement in protein binding with clinical significance.	**04**
	(c)	Explain drug transport. Describe carrier mediated transport.	**05**
	(d)	Describe Noyes-Whitney theory for drug dissolution.	**05**
Q.5	(a)	What is renal function? What is its significance in dosage regimen?	**02**
	(b)	Differentiate absolute and relative bioavailability. Calculate these values for tablet based on given data. Tablet (Dose-100 mg Oral, AUC -20); Solution (Dose-100 mg Oral, AUC-30) and Injection (Dose-50 mg IV bolus, AUC- 50).	**04**
	(c)	Classify the methods for bioavailability measurement. Discuss the method based on plasma data.	**05**
	(d)	Describe Latin Square cross over design for bioequivalence study.	**05**
Q. 6	(a)	What is high solubility and high permeability w.r.t. BCS?	**02**
	(b)	Describe biowaiver based on BCS and dissolution.	**04**
	(c)	Discuss USP dissolution apparatus with specific uses.	**05**
	(d)	How dissolution data are compared? Describe comparison based on f_1 and f_2.	**05**
Q.7	(a)	Describe matrixing and bracketing in stability study.	**04**
	(b)	Write note: Drug distribution to blood brain barrier.	**04**
	(c)	Discuss plasma protein drug binding.	**04**
	(d)	What is gastric emptying? Describe its role in drug absorption.	**04**

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