Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm. – SEMESTER – VIII • EXAMINATION – SUMMER 2013

Subject Code: 280001 Date: 09-05-2013

Subject Name: Dosage Form design - II

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)**	Enumerate the factors affecting the designing of oral sustained release drug delivery systems and explain any one in detail.	**06**
	(b)	Discuss in brief on Cube route dissolution equation.	**05**
	(c)	The pKa value of aspirin was 3.5 in stomach fluid at pH 2.5. Calculate the ratio of ionized to unionized aspirin under this condition. Write the comment regarding absorption of aspirin from stomach.	**05**
Q.2	**(a)**	Discuss one compartment open model - i.v. infusion model and discuss the effect of loading i.v. injection dose. Describe the derivation of various pharmacokinetic parameters for the model.	**06**
	(b)	Write a note on: Microspheres.	**05**
	(c)	What dose is needed to maintain a therapeutic concentration of 10 μg/ml for 12 hours in a sustained release drug product? (i) Assume $t_{1/2}$ of the drug is 3.46 hr and V_D is 10 L. (ii) Assume $t_{1/2}$ of the drug is 1.73 hr and V_D is 5 L.	**05**
Q.3	**(a)**	Discuss method of residuals to calculate Absorption rate constant (ka) in one compartment open model extravascular administration.	**06**
	(b)	Describe osmotic pressure controlled systems in brief.	**05**
	(c)	Write a note on: Wagner-Nelson method used to estimate Absorption rate constant (ka).	**05**
Q.4	**(a)**	Describe the formulation of Transdermal drug delivery systems in brief.	**06**
	(b)	Discuss the Evaluation methods for Transdermal drug delivery systems.	**05**
	(c)	An antibiotic is to be given to an adult male patient (58 years, 75 Kg) by i.v. infusion. The elimination half-life is 8 hours and the apparent volume of distribution is 1.5 L/Kg. The drug is supplied in 60 ml ampoule at a drug concentration of 15 mg/ml. The desired steady-state drug concentration is 20 mcg/ml. What infusion rate, in ml per hour, would you recommend for this patient? What loading dose would you recommend for this patient and when? By what route of administration would you give the loading dose?	**05**
Q.5	**(a)**	Discuss gastro retentive drug delivery systems in detail.	**06**
	(b)	Describe liposomes as a drug delivery system in brief.	**05**
	(c)	Write a note on: Hydrogel.	**05**
Q. 6	**(a)**	Discuss on Wagner- Nelson and Loo-Riegelman method.	**06**
	(b)	Describe ocular drug delivery systems in brief.	**05**
	(c)	A drug has an elimination half-life of 8 hours and follows first-order elimination kinetics. If a single dose of 600 mg is given to an adult female patient (62 Kg) by rapid IV injection, what % of dose is lost in 24 hours assuming the apparent V_D is 400 mL/Kg? What is the expected plasma drug concentration (Cp) at 24 hours post dose?	**05**
Q.7	**(a)**	Discuss on Michaeles Menten Equation.	**06**
	(b)	Definition Clinical Pharmacokinetics and describe its scope.	**05**
	(c)	Describe the dosing adjustment in patients with renal failure.	**05**

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