Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-I Remedial Examination April 2010

Subject code: 910102

Subject Name: Pharmaceutical Formulation, Development & Biopharmaceutics.

Date: 06 / 04 /2010 **Time: 12.00 noon – 03.00 pm**

Instructions: **Total Marks: 80**

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1	(a)	What predictions could be made from crystallographic data in preformulation studies?	**06**
	(b)	What is preformulation data report and explain the contents that must be included in it?	**05**
	(c)	Write in detail about drug–excipient interaction occurrences during dosage form development.	**05**
Q.2	(a)	What is solubility? How solubility is predicted mathematically? Describe any two practical methods for solubility determination.	**06**
	(b)	Explain in detail mechanisms of cyclodextrin and buffers in solubility improvement of poorly soluble drug with appropriate examples	**05**
	(c)	Comment: a poorly water soluble drug Oxytetracycline is formulated for administration through IM route with use of 75:25 Propylene glycol: water combination.	**05**
Q.3	(a)	What is biological classification system? How it helps in finalizing formulation type and dissolution in-vivo drug profiles?	**06**
	(b)	Explain various factors to be considered in dissolution media and conditions determination.	**05**
	(c)	Explain dissolution data modeling for pharmacokinetic study. Write in detail about Higuchi model model.	**05**
Q.4	(a)	Explain in detail ICH guidelines for stability studies of new active pharmaceutical ingredient.	**06**
	(b)	What is photostability study? How it is performed? Explain regulatory requirements for the same.	**05**
	(c)	Comment: Accelerated stability studies do not provide data as precise as long term stability studies.	**05**
Q.5	(a)	What is bioequivalency? Explain methods for determination of the same.	**06**
	(b)	How transport across biomembrane of a drug is evaluated? What is its significance in formulation development?	**05**
	(c)	Write a short note on Waiver of Bioavailability/Bioequivalence Studies.	**05**
Q. 6	(a)	Explain pharmacokinetics of protein binding	**06**
	(b)	Describe role of pharmacokinetic studies in formulation development..	**05**
	(c)	A single IV dose of an antibiotic was given to a 50-kg woman at a	**05**

dose level of 20 mg/kg. Urine and blood samples were removed periodically and assayed for parent drug. Using the following data were obtained:

Time (hr)	**Plasma drug concentration (g/mL)**	***Average concentration of drug in urine* (mg)**
0.25	4.2	160
0.5	3.5	140
1	2.5	200
2	1.25	250
4	0.31	188
6	0.08	46

Determine excretion rate constant and plasma half life of drug.

Q.7 (a) Why IVIVC is an important stage in formulation development? Explain any two methods for correlation studies. **06**

(b) What is convolution? Explain various levels of in vivo in vitro correlations. **05**

(c) Write an essay on formulation and evaluation of sunscreen lotion. **05**

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