Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2015

Subject Code: 910102 Date: 31-12-2015

Subject Name: Pharmaceutical Formulation, Development and Biopharmaceutics

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)**	Discuss the applications of DTA, DSC, FTIR in drug excipient compatibility study with suitable examples.	**06**
	(b)	Give a brief account on residual limits of organic volatile impurities.	**05**
	(c)	Discuss physico chemical factors influencing preformulation.	**05**
Q.2	**(a)**	How to improve the solubility of poorly soluble API along with the advantages and disadvantages involved in the methods adopted?	**06**
	(b)	Write short notes on Winstor's theory of solubilisation.	**05**
	(c)	Give a brief account on ingradients to be avoided which may lead to carcinogenicy in hair dyes or Shampoo preparations.	**05**
Q.3	**(a)**	State the role of crystallinity and polymorphism in dissolution of drug.	**06**
	(b)	How dissolution medium is selected for new API? Explain discriminating and bio relevant dissolution media?	**05**
	(c)	Discuss the dissolution apparatuses used for floating drug delivery system.	**05**
Q.4	**(a)**	Discuss Matrixing and bracketing designs for stability testing of new drug products.	**06**
	(b)	Compare and contrast the accelerated and real time stability study.	**05**
	(c)	Give a brief account on applications of micro calorimetry.	**05**
Q.5	**(a)**	What is non linear pharmacokinetics? Discuss problems in qualifying non linear pharmacokinetics.	**06**
	(b)	Discuss the permeability and active drug transport across CACO-2 monolayers.	**05**
	(c)	Enumerate on physico chemical factors influencing drug absorption.	**05**
Q. 6	**(a)**	Write short notes on methods of establishing IVIVC.	**06**
	(b)	Detail out the formulation and evaluation methods of sunscreen lotions.	**05**
	(c)	Describe the preformulation study to be carried out for biotechnological derived products.	**05**

Q.7 **(a)** Calculate elimination rate constant, half life, renal elimination rate constant, fraction of drug excreted unchanged, renal and total clearance by excretion rate method by assuming one compartment intravenous bolus model. A single dose of a drug was given to a 50Kg person at a dose of 10mg per Kg. Urine samples were collected and unchanged drug content was estimated. **06**

Time of urine collection(hr.)	**Vol. of Urine(ml)**	**Concentration of unchanged drug in urine(mg/ml)**
2	120	1330
4	180	500
6	89	630
8	340	100
12	178	180
24	950	20

(b) Give a brief account on Plasma protein binding of drug. **05**

(c) Define bioequivalence. Explain methods available to find bioavailability. **05**

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