Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Ph. – SEMESTER I – EXAMINATION – SUMMER 2018

Subject Code: 910102 **Date: 05/05/2018**

Subject Name: PHARMACEUTICAL FORMULATION DEVELOPMENT & BIOPHARMACEUTICS

Time: 02:30PM TO 05:30PM **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 hydrotrophy with respect to solubilization.	**06**
	(b)	Discuss drug excipients compatibility study in context to preformulation studies.	**05**
	(c)	Discuss the importance of dissolution study and enlist various dissolution test apparatus as per (i) IP and (ii) USP respectively.	**05**
Q.2	**(a)**	Explain (i) biological half life and (ii) total body clearance in context to pharmacokinetic parameters.	**06**
	(b)	Enumerate the pharmaceutical factors affecting drug absorption and discuss disintegration time in said context.	**05**
	(c)	Write the objectives of stability study and enumerate the factors affecting stability of formulation.	**05**
Q.3	**(a)**	Discuss formulation of tooth paste.	**06**
	(b)	Write a note on levels of IVIVC.	**05**
	(c)	Discuss the rationale for selecting preferred polymorphs/crystalline form with respect to preformulation study.	**05**
Q.4	**(a)**	Write a note on compartment models.	**06**
	(b)	Explain four classes of BCS.	**05**
	(c)	Explain "Order of reaction". Define (i) zero order reaction and (ii) first order reaction and write examples and equation for calculating half life for each.	**05**
Q.5	**(a)**	Enumerate the methods of studying bioavailability and with the help of diagram, explain the importance of three major parameters of urinary excretion data obtained with single dose study.	**06**
	(b)	Write the criteria for obtaining valid urinary excretion data.	**05**
	(c)	Define IVIVC and discus its purposes.	**05**
Q. 6	**(a)**	Define preformulation and write the objectives of preformulation studies. Give full forms of the following: (i) DSC (ii) XRD (iii) FTIR (iv) OVIs (v) DTA and (vi) NCEs.	**06**
	(b)	Write a note on photo stability testing.	**05**
	(c)	Explain dissolution profile. Discuss the importance of comparison of the same and explain model independent method involving f_1 and f_2.	**05**
Q.7	**(a)**	Define shampoo and write its requirements. Enumerate shampoo additives.	**06**
	(b)	Discuss the techniques for stabilization of pharmaceutical products against atmospheric oxygen.	**05**
	(c)	Discuss hygroscopicity in context to preformulation study.	**05**