Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph. - SEMESTER–8 • EXAMINATION – SUMMER-2018

Subject Code:2280011 Date: 09/05/2018

Subject Name: Drug Approval Process

Time:10:30am to 01:30pm 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)**	Explain various phases of drug development.	**06**
	(b)	What is investigational new drug (IND)? Explain types of INDs.	**05**
	(c)	Enlist various section of IND application. Give Format of application.	**05**
Q.2	**(a)**	What is Orange Book ? List the contents of orange book. Describe coding system for therapeutic equivalence evaluation.	**10**
	(b)	Define bioequivalence. How is it performed? State statistical criteria of Bioequivalence?	**06**
Q.3	**(a)**	How to make a FOIA request? Which information is exempted from FOIA?	**06**
	(b)	What is DMF? Enlist type of DMF. Discuss DMF Type II.	**05**
	(c)	Write note on Inactive Ingredients Guidelines.	**05**
Q.4	**(a)**	Write short note on ANVISA.	**06**
	(b)	Discuss the WHO certification scheme for pharmaceutical products.	**05**
	(c)	Write brief note on TGA.	**05**
Q.5	**(a)**	States the goals of NDA. Discuss general requirements of NDA.	**06**
	(b)	Prepare a NDA chart showing NDA review process	**05**
	(c)	Write note on supplement NDA.	**05**
Q. 6	**(a)**	Outline steps taken by CDSCO in February 2015 in making its services responsive, effective and transparent.	**06**
	(b)	Write a note on ANDA. Explain the concept of PARA I to IV filling.	**05**
	(c)	What is SUPAC? Discuss the SUPAC guidelines for Immediate release dosage forms.	**05**
Q.7	**(a)**	What is CTD? Discuss structure of CTD. How it differs from eCTD.	**06**
	(b)	Describe the activity regulated by MHRA.	**05**
	(c)	How approval of bio-similar differs from NDA?	**05**

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