Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM – SEMESTER – 8- EXAMINATION –WINTER - 2018

Subject Code: 2280011 Date: 28/11/2018

Subject Name: Drug Approval Process

Time: 02:30 PM TO 05:30 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)**	What is SUPAC? Explain the level of changes in SUPAC-MR.	**06**
	(b)	Discuss guideline for the post approval changes in SUPAC – IR	**05**
	(c)	Explain in brief SUPAC – SS.	**05**
Q.2	**(a)**	Explain the concept of para I to IV and generic exclusivity.	**06**
	(b)	Explain in brief regulatory agency ICH.	**05**
	(c)	Write a note on CTD.	**05**
Q.3	**(a)**	Define new drug according to FDA. Explain in detail the new drug development process with the time course for each phase.	**06**
	(b)	What are Bio – similar? How approval of bio similar differs from NDA.	**05**
	(c)	Prepare a NDA chart showing NDA review process.	**05**
Q.4	**(a)**	Define DMF. Explain it briefly.	**06**
	(b)	Describe the activity regulated by TGA.	**05**
	(c)	Write note on Purple book.	**05**
Q.5	**(a)**	Discuss special emphasis on approval under 505 (b) (2).	**06**
	(b)	What is INDA? Give the contents of investigation broucher of INDA.	**05**
	(c)	Explain registration process of new drug under ANVISA.	**05**
Q. 6	**(a)**	What is CDSCO? Outline steps taken by CDSCO in 2015 in making its services responsive, effective and transparent.	**06**
	(b)	Explain in detail the sources of new drug.	**05**
	(c)	What is bioequivalence? State statistical criteria of Bioequivalence.	**05**
Q.7	**(a)**	Write note on freedom of Information.	**06**
	(b)	Discuss the WHO certification scheme for pharmaceutical products.	**05**
	(c)	Describe content and steps of ANDA.	**05**

****