Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm - SEMESTER–VIII • EXAMINATION – SUMMER 2017

Subject Code: 2280011 Date: 09/05/2017

Subject Name: Drug Approval Process

Time: 10:30 AM to 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)**	What is CCDSCO? Outline steps taken by CDSCO in 2015 in making its services responsive, effective and transparent.	**06**
	(b)	Describe content & steps of ANDA.	**05**
	(c)	What is SUPAC? Discuss the SUPAC guidelines for Immediate release dosage forms.	**05**
Q.2	**(a)**	How to make a request under FOIA? Which information is exempted from FOIA?	**06**
	(b)	Enlist type of Drug Master File and discuss DMF Type II.	**05**
	(c)	Write note on CDER guidelines for inclusion of Inactive Ingredients in formulation.	**05**
Q.3	**(a)**	States the goals of NDA. Discuss general requirements of NDA.	**06**
	(b)	Prepare a NDA chart showing NDA review process	**05**
	(c)	Explain provisions of supplement NDA.	**05**
Q.4	**(a)**	What are common Technical documents required for new drug approval? Discuss structure of CTD. How it differs from eCTD.	**06**
	(b)	What are Bio-similar? How approval of bio-similar differs from NDA?	**05**
	(c)	Describe the activity regulated by USFDA.	**05**
Q.5	**(a)**	Define Drug. Outline 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. 6	**(a)**	What is ANVISA? How it differs from ICH guidelines for drug approval.	**06**
	(b)	Discuss the WHO certification scheme for pharmaceutical products.	**05**
	(c)	Write brief note on TGA.	**05**
Q.7	**(a)**	Write note on content and application of Orange Book.	**08**
	(b)	What is bioequivalence? How is it performed? State statistical criteria of Bioequivalence?	**08**

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