Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– 8 EXAMINATION – WINTER -2019

Subject Code: 2280011 **Date: 27-11-2019**

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)**	Discuss in brief about various phases of drug development and approval.	**06**
	(b)	Write note on orange book.	**05**
	(c)	What is TGA? Discuss structure of TGA.	**05**
Q.2	**(a)**	Explain the approval process of new drug under 505 (b) (2).	**06**
	(b)	Give overview on freedom of information.	**05**
	(c)	What is drug master file? Discuss various parts of DMF.	**05**
Q.3	**(a)**	What is NDA? Explain in brief about content and format.	**06**
	(b)	What is CTD? Explain the modules of CTD.	**05**
	(c)	Discuss the analytical validation guideline as per ICH.	**05**
Q.4	**(a)**	What is CDSCO? Discuss guideline for form submission under it.	**06**
	(b)	Write note on inactive ingredient guidelines.	**05**
	(c)	Discuss registration of USFDA for new drug approval process.	**05**
Q.5	**(a)**	What is SUPAC –IR? Discuss regarding post approval changes in SUPAC- IR.	**06**
	(b)	Discuss about component and composition of SUPAC –SS.	**05**
	(c)	Explain registration process of new drug under ANVISA.	**05**
Q. 6	**(a)**	Define new drug according to FDA. Explain in detail the new drug development process with the time course for each phase.	**06**
	(b)	Enlist and explain different types of IND.	**05**
	(c)	What is MHRA? Discuss aim and objective of MHRA.	**05**
Q.7	**(a)**	Discuss general requirement of NDA. Discuss in brief about provisions of supplement NDA.	**06**
	(b)	What are Bio – Similar? How approval of bio-similar differes from NDA?	**05**
	(c)	Discuss regarding guideline for funding research and studies.	**05**

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