Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– VIII- EXAMINATION – SUMMER-2016

Subject Code:2280011 **Date:10/05/2016**

Subject Name: Drug Approval Process

Time:10:30am.- 1:30pm. **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)**	Define new drug according to FDA. Explain in detail the new drug development process with the time course for each phase.	**06**
	(b)	Explain in detail the sources of new drug.	**05**
	(c)	Enlist and explain methods of drug discovery.	**05**
Q.2	**(a)**	Define DMF. Enlist and explain types of DMF.	**06**
	(b)	Write short note on orange book.	**05**
	(c)	Write short note on inactive ingredient guide and FOI.	**05**
Q.3	**(a)**	Explain the concept of para I to IV filing.	**06**
	(b)	Explain the approval process of new drug under 505 (b) (2).	**05**
	(c)	What is INDA? Give the contents of investigation broucher of INDA.	**05**
Q.4	**(a)**	Define the following: 1. Purple book 2. ICH 3. MCA 4. Biosimilarity 5. WHO 6. MHRA	**06**
	(b)	Explain registration process of new drug under ANVISA.	**05**
	(c)	What is TGA? Give the structure of TGA.	**05**
Q.5	**(a)**	What is CTD? Write in brief about CTD.	**06**
	(b)	Write short note on US- FDA.	**05**
	(c)	Write short note on WHO.	**05**
Q. 6	**(a)**	What is SUPAC? Explain the level of changes in SUPAC- MR.	**06**
	(b)	Guideline for the post approval changes in SUPAC-IR.	**05**
	(c)	Explain in brief SUPAC-SS.	**05**
Q.7	**(a)**	Explain in brief about content and format of NDA.	**06**
	(b)	Write short note on bio-similarity.	**05**
	(c)	Enlist and explain different types of IND.	**05**

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