Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM - SEMESTER–1 EXAMINATION – SUMMER-2019

Subject Code: MPH104T **Date: 04/06/2019**

Subject Name: Regulatory Affair

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)**	Explain IND submission for world wide.	**06**
	(b)	Write a note on ANDA. Explain PARA I to IV filling in ANDA.	**05**
	(c)	Give details note on NDA.	**05**
Q.2	**(a)**	Define CTD and eCTD. Explain in detail.	**06**
	(b)	What is DMF? Write a note on Type of DMF.	**05**
	(c)	Explain in details Master Formula Record. (MFR).	**05**
Q.3	**(a)**	Describe CFR 21 (code of federal regulation) in details.	**06**
	(b)	Explain guidelines of ICH-Q.	**05**
	(c)	Give important of CRO. What about out sourcing of BA & BE studies to CRO?	**05**
Q.4	**(a)**	Explain the guideline of TGA for generic products.	**06**
	(b)	What are CMC regulatory affairs? Describe post approval regulatory affairs.	**05**
	(c)	Define orange book. Explain investigator brochure (IB).	**05**
Q.5	**(a)**	What is dossier? Explain regulatory requirements of dossier for ROW countries.	**06**
	(b)	Explain regulation for combination product & medical devices in various countries.	**05**
	(c)	Give details note on MHRA.	**05**
Q. 6	**(a)**	Explain the various components of FDA.	**06**
	(b)	What is Post Marketing Surveillance (PMS)? Give it's important in clinical trials.	**05**
	(c)	How to develop clinical trials protocol at institute level?	**05**
Q.7	**(a)**	Explain WAXMAN-HATCH ACT. What its economic impact on the society.	**06**
	(b)	Give in details of Pharmacovigilence safety monitoring in Clinical Trials.	**05**
	(c)	Describe HIPAA-new requirement to clinical study process.	**05**

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