Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM - SEMESTER–2 EXAMINATION – SUMMER-2019

Subject Code: MPT203T Date: 31/05/2019

Subject Name: Pharmaceutical regulatory affaires

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)**	Discuss the importance of documentation in Pharmaceutical industry.	**06**
	(b)	Explain in brief about code of federal regulation title 21.	**05**
	(c)	Write the functions of CROs. Write a brief note on outsourcing of BA BE study.	**05**
Q.2	**(a)**	What are the types of ANDA? Discuss the guidance documents required to file ANDA.	**06**
	(b)	Explain in detail about content, format and review cycle for NDA filing.	**05**
	(c)	Write a detailed note on guideline for data integrity and quality matrices.	**05**
Q.3	**(a)**	Define CTD & eCTD. Explain modules of CTD.	**06**
	(b)	Explain the objective of TGA regulation. Discuss the TGA guideline for OTC product.	**05**
	(c)	Write a detailed note on QSEM guideline.	**05**
Q.4	**(a)**	Explain format and content of IND in detail.	**06**
	(b)	Give the comparison between in IND, NDA and ANDA for non-clinical drug development.	**05**
	(c)	Write the different steps of ANDA regulatory approval process.	**05**
Q.5	**(a)**	Give the composition, functions and responsibilities of Institutional review board.	**06**
	(b)	Discuss in brief about schedule Y for clinical trial development.	**05**
	(c)	What are the regulations related with combination products?	**05**
Q. 6	**(a)**	Write a short note on SUPAC for non-sterile semisolid dosage form with suitable example.	**06**
	(b)	Write a brief note on BMR for tablet manufacturing using wet granulation method.	**05**
	(c)	Describe in brief the responsibility of international conference of harmonization.	**05**
Q.7	**(a)**	Write a brief note on Hatch-Waxman act and amendments including its benefits.	**06**
	(b)	Short note on investigator brochure (IB) of Non clinical drug development	**05**
	(c)	Explain drug master file in brief with its type.	**05**

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