Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: MRA102T Date: 30/05/2019

Subject Name: Documentation and Regulatory Writing

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)**	Enlist and explain modules of CTD.	**06**
	(b)	Write a note on drug master files.	**05**
	(c)	Discuss FDA inspection and enforcement.	**05**
Q.2	**(a)**	Write note on auditing strategies, preparation and conducting audit.	**06**
	(b)	Discuss ISO risk management standard.	**05**
	(c)	Explain certificate of analysis (CoA) with example.	**05**
Q.3	**(a)**	Discuss at length post approval changes (SUPAC).	**06**
	(b)	Write a short note on product development report in pharmaceutical industry.	**05**
	(c)	Discuss warning letters with example.	**05**
Q.4	**(a)**	Write a note on quality systems requirements for national good manufacturing practice inspectorates.	**06**
	(b)	Discuss Asian CTD formats (ACTD) submission.	**05**
	(c)	What is audit? Explain types of audits.	**05**
Q.5	**(a)**	Write a note on inspection of pharmaceutical manufacturers.	**06**
	(b)	Explain post approval labeling changes in product life cycle management.	**05**
	(c)	Discuss about introduction, overview, contents and organization of dossier.	**05**
Q. 6	**(a)**	Describe inspection of drug distribution channels.	**06**
	(b)	Discuss auditing of manufacturing facilities by regulatory agencies.	**05**
	(c)	Compare master formula record and batch manufacturing record.	**05**
Q.7	**(a)**	Write a note on electronic CTD submissions.	**06**
	(b)	Discuss corrective and preventive action (CAPA).	**05**
	(c)	Explain dossier submission in sugam system of CDSCO.	**05**

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