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GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER -2018

Subject Code: MRA102T **Date: 05/05/2018**

Subject Name: Documentation and Regulatory Writing

Time: 02:30PM TO 05:30PM **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)**	Give objectives of Drug master file (DMF). Compare US and European Drug master file preparation.	**06**
	(b)	Discuss in detail Certificate of Analysis (CoA) with its purpose and scope	**05**
	(c)	Write a note on Product Development Report	**05**
Q.2	**(a)**	What do mean by BMR. Explain various steps involving to complete BMR.	**06**
	(b)	Write a note on Product Development Plan.	**05**
	(c)	What do you mean by Batch Reconciliation? Explain its objective and task performed during batch reconciliation.	**05**
Q.3	**(a)**	What do you mean by CTD? Discuss modules of CTD.	**06**
	(b)	What do you mean by eCTD? Give its advantages and disadvantages.	**05**
	(c)	Discuss Non eCTD electronic submissions (NeeS) with suitable example.	**05**
Q.4	**(a)**	Define audits. Enlists types of audits. Explain in brife Audit policy.	**06**
	(b)	Write a short note on Company Auditor.	**05**
	(c)	Discuss in detail submission process in SUGAM system of CDSCO.	**05**
Q.5	**(a)**	Discuss in detail about preparation for pre-approval inspections of FDA.	**06**
	(b)	Discuss in detail Auditing strategies.	**05**
	(c)	Explain in brief Second Party Audits and Third Party Audits.	**05**
Q. 6	**(a)**	Describe procedure for Inspection of drug distribution channels.	**06**
	(b)	Enlist the processing steps for quality systems requirements for national good manufacturing practice inspectorates. Explain purpose and scope for the same.	**05**
	(c)	What do you mean by CAPA? Explain purpose of CAPA.	**05**
Q.7	**(a)**	Explain SUPAC guideline to Industry for Immediate Release Solid Oral Dosage Forms with respect to site change.	**06**
	(b)	Define recall. Explain recall procedure for drug product.	**05**
	(c)	Describe in detail ISO risk management standard.	**05**

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