Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Ph. - SEMESTER–II • EXAMINATION –SUMMER-2018

Subject Code: MPT203T **Date: 18/05/2018**

Subject Name: Pharmaceutical Regulatory Affairs

Time: 10:30 am to 1:30 p.m. **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)**	Differentiate between Drug Master File and Master Formula Record. Write a note on Drug Master Formula Record.	**06**
	(b)	Write a short note on batch manufacturing records	**05**
	(c)	Discuss objectives and scope of Documentation.	**05**
Q.2	**(a)**	Write a short note on post marketing surveillance.	**06**
	(b)	Write a note on Hutch Waxman Act and Amendments for generic drugs.	**05**
	(c)	What is mean by bioequivalence and explain drug product assessment related to BE.	**05**
Q.3	**(a)**	Define CTD & eCTD. Explain modules of CTD.	**06**
	(b)	What is CMC? What are the critical elements of CMC? Explain how CMC is specific to product.	**05**
	(c)	Explain the concept of ANDA and ANDA review process.	**05**
Q.4	**(a)**	Differentiate INDA and ANDA. Describe various type of INDA	**06**
	(b)	Discuss the phases of investigation in context to IND.	**05**
	(c)	Write a note on scale up process for post approval changes with respect to composition and content.	**05**
Q.5	**(a)**	Explain classification of drugs in NDA. Discuss the guidance documents required to prepare NDAs.	**06**
	(b)	Explain the scope of TGA regulations. Discuss the TGA guidelines for OTC product.	**05**
	(c)	Define i) IND (ii) CMC (iii) IND safety reports (iv) IND annual report (v) Institutional review board.	**05**
Q. 6	**(a)**	Describe evaluation of the stability data as per ICH guidelines.	**06**
	(b)	What is Data integrity? What are the purpose and guidelines for Data integrity?	**05**
	(c)	Write a note on Investigator Brochure.	**05**
Q.7	**(a)**	Discuss development of clinical trial protocol.	**06**
	(b)	Give an account on FDA guidelines on clinical trials, review and approval of clinical study.	**05**
	(c)	Write short note on Code of Federal regulation.	**05**

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