Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm - SEMESTER–III • EXAMINATION – SUMMER-2016

Subject Code: 1931501 **Date: 27/05/2016**

Subject Name: Drug regulation and Regulatory Authority

Time: 2:30 PM to 5:30 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 in detail Drug Master File.	**06**
	(b)	Write a note on medical device registration as per 510k .	**05**
	(c)	Explain the format and contents of NDA.	**05**
Q.2	**(a)**	Write a note on WHO certification scheme on Quality of Pharmaceutical products.	**06**
	(b)	Explain the Procedure for price fixing of Drug substance and Drug Product.	**05**
	(c)	Write a note on National Formulary of India.	**05**
Q.3	**(a)**	Explain the Standard format of Monograph as per IP.	**06**
	(b)	Give Emphasis on IP Review Process.	**05**
	(c)	Write a note on Site Master File.	**05**
Q.4	**(a)**	Write a note on GCP as per US.	**06**
	(b)	Define Pharmacovigilance. Explain ADR reporting system in India and US.	**05**
	(c)	Write a note on Toxicological studies as per ICH guidelines.	**05**
Q.5	**(a)**	Classify medical device. Explain in detail PMA process in detail.	**06**
	(b)	Define Haemovigilance. Explain Adverse event reporting system as per India.	**05**
	(c)	Explain labeling requirements for drugs as per D &C act.	**05**
Q. 6	**(a)**	Explain Objectives and functions of CDL and DTAB.	**06**
	(b)	Write a note on NDA as per EUDRA guidelines.	**05**
	(c)	Explain the process involved in Harmonization of Pharmacopieal standards.	**05**
Q.7	**(a)**	Explain the clinical evaluation process as per US and Europe.	**06**
	(b)	Explain WHO guidelines with emphasis on International registration.	**05**
	(c)	Write a note on electronic CTD.	**05**

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