Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1931501 **Date: 23/11/2016**

Subject Name: Drug regulation and Regulatory Authority

Time:10.30 am – 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)**	Explain ICH GCP guidelines. Give a brief account on function of IRB/IEC.	**06**
	(b)	Explain the organization and functions of NPPA.	**05**
	(c)	Write a note on IP review process.	**05**
Q.2	**(a)**	Explain the role of PDG and Expert working group on harmonization of pharmacopeial standards.	**06**
	(b)	Explain New Drug Application and approval process in India as per CDSCO.	**05**
	(c)	Explain difference between site master file and drug master file.	**05**
Q.3	**(a)**	Give comparative evaluation of ADR reporting system between in US and India.	**06**
	(b)	Give emphasis on storage requirement, supply procedures and precautionary measures for blood and blood related products as per India.	**05**
	(c)	Explain the format and content of monograph as per IP.	**05**
Q.4	**(a)**	Write a note on preclinical evaluation process.	**06**
	(b)	Explain WHO certification scheme.	**05**
	(c)	Explain the Import Export regulation in India.	**05**
Q.5	**(a)**	Explain the organization and functions of CDL and DTAB.	**06**
	(b)	Write note on NF of US.	**05**
	(c)	Explain the content and format of NDA.	**05**
Q. 6	**(a)**	Compare the regulatory requirements for application of new drugs in US and Europe.	**06**
	(b)	Classify medical device and explain 510(K) process for registration of medical devices.	**05**
	(c)	Explain registration process for PMA.	**05**
Q.7	**(a)**	Explain the documents required for registration of medical device as per US.	**06**
	(b)	Define reference standards. Explain the procedure for reference listed drugs.	**05**
	(c)	What is ICH? Give a brief account on different ICH guidelines.	**05**

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