Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – WINTER 2013

Subject Code: 1931501 **Date: 11-12-2013**

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)**	Describe how pharmacy profession is regulated in India.	**06**
	(b)	What is the purpose of 'The pharmacy Act 1948? Describe the functions of pharmacy council of India.	**05**
	(c)	Write a note on: National Pharmaceutical Pricing Authority.	**05**
Q.2	**(a)**	Write a brief account on Indian Pharmacopoeia.	**06**
	(b)	What is IP reference substance? Give detail note on reference spectra in IP, with their uses.	**05**
	(c)	Write a note on: Haemovigilance programme.	**05**
Q.3	**(a)**	Discuss the guidelines for formation of monograph of IP.	**06**
	(b)	Write a brief account on pharmacovigilance programme of India.	**05**
	(c)	Write a note on: New Drug Application and approval in India from CDSCO as per schedule Y and related provisions.	**05**
Q.4	**(a)**	Describe the specific requirements and contents of an NDA.	**06**
	(b)	Give brief comparative outlines of guidelines for filing New Drug Application in US & EU.	**05**
	(c)	What is a site master file? How it differs from DMF? Explain out of specification in brief.	**05**
Q.5	**(a)**	What is ICH? Discuss the importance of ICH guidelines? Give a brief account on different ICH guidelines.	**06**
	(b)	Describe WHO guidelines for pharmaceutical product registration in brief.	**05**
	(c)	Discuss the guidelines for toxicological studies as per ICH.	**05**
Q. 6	**(a)**	What is Good Clinical Practice (GCP)? What are the goals of GCP?	**06**
	(b)	Discuss the principles of ICH-GCP.	**05**
	(c)	Who is responsible for GCP compliance? How does FDA implement GCP?	**05**
Q.7	**(a)**	Discuss the regulations on the medical devices in India.	**06**
	(b)	Describe the registration process for medical devices in India.	**05**
	(c)	Classify the medical devices.	**05**

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