Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – SUMMER • 2015

Subject Code: 1931501 **Date: 13-05-2015**

Subject Name: Drug Regulation and Regulatory Authority

Time: 02:30 pm - 05:30 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)**	Give an account on fixation of retail price of formulations as per drug price control Order, 1955. Explain the formula used for calculation of retail price of drug formulations.	**06**
	(b)	Give historical outline for Indian Pharmacopoeia. Discuss role of IP committee in publication of Indian Pharmacopoeia.	**05**
	(c)	Discuss a common framework required in medical device regulation.	**05**
Q.2	**(a)**	Write objectives of ICH E8 guidelines. Discuss development plan for clinical trials for special population.	**06**
	(b)	Write a brief note on IP reference substance and its spectra.	**05**
	(c)	Write eligibility criteria required for participating in WHO certification scheme.	**05**
Q.3	**(a)**	Give an account on FDA guidelines on clinical trials, review and approval of clinical study.	**06**
	(b)	Discuss drug pharmacokinetic studies on elderly patients as per ICH E7 guidelines.	**05**
	(c)	Write principle and goals of Good clinical practice.	**05**
Q.4	**(a)**	What is Drug Technical Advisory Board? Discuss their constitution and functions.	**06**
	(b)	Write a note on WHO certification scheme	**05**
	(c)	Write in detail objectives and function of Pharmacy Act 1948	**05**
Q.5	**(a)**	What are the objectives of Drug master file (DMF)? Compare US and European Drug master file preparation.	**06**
	(b)	Describe the organization of the Common Technical Document.	**05**
	(c)	Write a note on Haemovigilance programme in India.	**05**
Q. 6	**(a)**	Discuss content and format of NDA as per the US FDA.	**06**
	(b)	What should Member States and regional organizations possess in order to issue a Certificate for a Pharmaceutical Product (CPP) to support the export pharmaceutical products?	**05**
	(c)	Write provisions of import of drug as per D& C act, 1940.	**05**
Q.7	**(a)**	Classify medial devices and discuss in brief registration process of medical device in India.	**06**
	(b)	Discuss the process of IP monographs development.	**05**
	(c)	Define Site master file. Explain the structure of Site master file.	**05**

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