Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – III • EXAMINATION – WINTER • 2014

Subject Code: 1931501 Date: 06-12-2014

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)**	Write the objectives of Drug and cosmetics act? Who are the members of DTAB? Write the functions of DTAB.	**8**
	(b)	What is the purpose of 'The Pharmacy Act 1948'? Describe the functions of PCI.	**8**
Q.2	**(a)**	Write a note on import of drugs as per D & C act.	**06**
	(b)	Discuss briefly contents of NDA applications as per US-FDA.	**10**
Q.3	**(a)**	Describe the functions of Central Drug Laboratory.	**06**
	(b)	Discuss goals and objectives of pharmacovigilance programme of India. Who are committee members? Write risk management of PvPI.	**10**
Q.4	**(a)**	Describe briefly content of Drug Master File.	**06**
	(b)	Write a note on Guidelines on data required to be submitted for approval of clinical trials in India from CDSCO.	**10**
Q.5	**(a)**	Write objectives of Indian Pharmacopoeia Commission. Give basic guidelines for formation of Monograph. Discuss format of monograph.	**06**
	(b)	Write a note on WHO certification scheme.	**05**
	(c)	Write key elements of the essential requirements from the Regulatory Strategy for Medical Devices in EU.	**05**
Q. 6	**(a)**	Write a note on the drug prices controls order. Write functions of NPPA briefly.	**06**
	(b)	Write objectives and general principle of ICH E8 guideline for general considerations for clinical trials.	**05**
	(c)	Give purpose, scope of Site Master File (SMF). Write a note on guidelines for drafting a SMF.	**05**
Q.7	**(a)**	Write a note on Haemovigilance programme with objectives.	**06**
	(b)	Describe overall organization of the Common Technical Document (CTD).	**05**
	(c)	Enumerate ICH guideline on toxicological studies. Discuss ICH Guideline on the need for carcinogenicity studies of pharmaceuticals.	**05**

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