Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm - SEMESTER– VII EXAMINATION – SUMMER-2016

Subject Code: 2270010 **Date: 13/05/2016**

Subject Name: Pharmacovigilance

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)**	Discuss role of pharmacist in detecting, assessing and managing ADR.	**06**
	(b)	Write a note on WHO international drug monitoring programme.	**05**
	(c)	Describe hematological ADRs with suitable examples.	**05**
Q.2	**(a)**	Describe cohort event monitoring of ADR.	**08**
	(b)	What are medication errors? Describe medication errors with examples. Discuss role of pharmacist in prevention of medication errors.	**08**
Q.3	**(a)**	Write alphabetic classification of adverse drug reactions. Describe pharmacokinetic mechanisms of type-A adverse drug reactions in detail.	**08**
	(b)	Write type and structure of Individual Case Safety Report (ICSR) as per ICH E2B guidelines.	**08**
Q.4	**(a)**	Compare and contrast between WHO and Naranjo's casualtiy assessment scale.	**10**
	(b)	Define Signal. Discuss sources and scope of signal detection.	**06**
Q.5	**(a)**	Explain spontaneous reporting of adverse drug reactions with suitable examples. What are merits and demerits of spontaneous reporting?	**08**
	(b)	Enumerate adverse effects of various antibiotics in brief. Discuss super-infection, gray baby syndrome, Fanconi syndrome and red-men syndrome in brief.	**08**
Q. 6	**(a)**	i. Explain: Thalidomide tragedy. ii. Differentiate between Adverse drug reaction and Adverse event. iii. Explain: Idiosyncrasy.	**06**
	(b)	Explain serious adverse events. How it is managed and reported to regulatory agency?	**05**
	(c)	Write current Pharmacovigilance programme in India. State the benefits in brief.	**05**
Q.7	**(a)**	Write in brief about Phase-IV of clinical trials (Post-marketing surveillance). Discuss need of pharmacovigilance in clinical trials.	**06**
	(b)	What are Spurious, Falsely labelled, Falsified, Counterfeit (SFFC) medicines? What encourages counterfeiting of medicines? What should be done to ensure the safety, efficacy and quality of medicines?	**10**

****