Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– 7 EXAMINATION – SUMMER -2019

Subject Code: 2270010 Date: 20-05-2019

Subject Name: Pharmacovigilance

Time: 02:30 PM TO 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)**	Discuss the contents and structure of Individual Case Safety Reports (ICSRs),	**06**
	(b)	Write in brief about Phase-IV of clinical trials (Post-marketing surveillance).	**05**
	(c)	Describe pattern and scale of counterfeiting.	**05**
Q.2	**(a)**	i. Explain: Thalidomide tragedy. ii. Differentiate between Adverse drug reaction and Adverse event.	**06**
	(b)	Write a note on adverse drug reactions of kidney.	**05**
	(c)	Define SRS. Discuss potential and limitation of SRS.	**05**
Q.3	**(a)**	Define ADRs. Explain the types of ADRs with suitable examples.	**06**
	(b)	Write role of pharmacist in the management of adverse drug reactions.	**05**
	(c)	Write methods of detection of medication errors.	**05**
Q.4	**(a)**	Definition of substandard/spurious/falsely labelled/falsified/counterfeit medicines.	**06**
	(b)	Describe pharmacogenetic causes of ADRs.	**05**
	(c)	Define Signal. Discuss sources and scope of signal detection.	**05**
Q.5	**(a)**	Write types of medication errors with examples.	**06**
	(b)	Write a note on naranjo's casualtiy assessment scale.	**05**
	(c)	Explain spontaneous reporting of adverse drug reactions with suitable examples.	**05**
Q. 6	**(a)**	Write a note on pharmacovigilance in clinical trial	**06**
	(b)	Write role ICSRs in Pharmacovigilance	**05**
	(c)	Discuss forms and formats of SRS.	**05**
Q.7	**(a)**	Explain current methods of pharmacovigilance.	**06**
	(b)	Write a note on pharmacovigilance regulation in india.	**05**
	(c)	What are merits and demerits of spontaneous reporting?	**05**

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