Seat No.: _____   Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER– 7 EXAMINATION – WINTER -2019

Subject Code: 2270010   **Date: 28-11-2019**
Subject Name: Pharmacovigilance
Time: 10:30AM TO 01:30PM   **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 forms and formats of SRS.	**06**
	(b)	Define Signal. Discuss sources and scope of signal detection.	**05**
	(c)	Discuss potential and limitation of SRS.	**05**
Q.2	**(a)**	Define : substandard/spurious/falsely labelled/falsified/counterfeit (SSFFC) medicines,	**06**
	(b)	Explain Pattern and scale of counterfeiting,	**05**
	(c)	Write methods of detection of medication errors.	**05**
Q.3	**(a)**	Explain current methods of Pharmacovigilance.	**06**
	(b)	Write a note on Pharmacovigilance in clinical trial	**05**
	(c)	Write a note on Pharmacovigilance regulation in india.	**05**
Q.4	**(a)**	Write role of ICSRs in pharmacovigilance	**06**
	(b)	Write a note on observational studies	**05**
	(c)	Describe structure, validity and assessment of ICSRs in Pharmacovigilance	**05**
Q.5	**(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)	Differentiate between Adverse drug reaction and Adverse event.	**05**
Q. 6	**(a)**	What are merits and demerits of spontaneous reporting?	**06**
	(b)	Write a note on adverse drug reactions of Liver	**05**
	(c)	Write a note on Dermatological ADRs.	**05**
Q.7	**(a)**	Write a note on naranjo's causality assessment scale.	**06**
	(b)	Explain spontaneous reporting of adverse drug reactions with suitable examples.	**05**
	(c)	Write mechanism of ADRs with examples.	**05**

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