Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm. - SEMESTER– VII EXAMINATIONS – WINTER • 2015

Subject Code: 2270010 Date: 16-12-2015

Subject Name: Pharmacovigilance

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)**	Describe briefly current methods of pharmacovigilance.	**06**
	(b)	Write a brief note on causality assessment of ADRs.	**05**
	(c)	Define Signal. Discuss sources and scope of signal detection.	**05**
Q.2	**(a)**	What are duties and responsibilities of Clinical Pharmacist in ADR reporting? Give sample formats for ADR reports. Describe the role of pharmacist in detection and management of ADRs.	**10**
	(b)	Describe with suitable examples dermatological ADRs.	**06**
Q.3	**(a)**	Write a brief account on pharmacovigilance programme of India.	**08**
	(b)	What are medication errors? Give types of medication errors. List out medication errors with examples. Write in brief about causes and prevention of medication errors.	**08**
Q.4	**(a)**	Explain the types of adverse drug reactions (ADRs) with mechanism of ADRs.	**08**
	(b)	Explain the terms: Substandard and counterfeit medicines. Describe pattern and scale of counterfeiting.	**08**
Q.5	**(a)**	Write a note on pharmacovigilance in clinical trials.	**08**
	(b)	Write a merits and demerits of spontaneous ICSR reporting systems. Discuss format of spontaneous reporting system.	**08**
Q. 6	**(a)**	What is ICSRs? Describe Validity, assessment and role of ICSRs in pharmacovigilance.	**08**
	(b)	Explain serious adverse events. How it is managed and reported to regulatory agency?	**08**
Q.7	**(a)**	Write a note on adverse hepatic reactions.	**06**
	(b)	Write a note on WHO international drug monitoring programme.	**05**
	(c)	Distinguish between adverse drug events and adverse drug reactions.	**05**

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