

**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.

<b>Q.1</b>	(a) Discuss forms and formats of SRS.	<b>06</b>
	(b) Define Signal. Discuss sources and scope of signal detection.	<b>05</b>
	(c) Discuss potential and limitation of SRS.	<b>05</b>
<b>Q.2</b>	(a) Define : substandard/spurious/falsely labelled/falsified/counterfeit (SSFFC) medicines,	<b>06</b>
	(b) Explain Pattern and scale of counterfeiting,	<b>05</b>
	(c) Write methods of detection of medication errors.	<b>05</b>
<b>Q.3</b>	(a) Explain current methods of Pharmacovigilance.	<b>06</b>
	(b) Write a note on Pharmacovigilance in clinical trial	<b>05</b>
	(c) Write a note on Pharmacovigilance regulation in india.	<b>05</b>
<b>Q.4</b>	(a) Write role of ICSRs in pharmacovigilance	<b>06</b>
	(b) Write a note on observational studies	<b>05</b>
	(c) Describe structure, validity and assessment of ICSRs in Pharmacovigilance	<b>05</b>
<b>Q.5</b>	(a) Define ADRs. Explain the types of ADRs with suitable examples.	<b>06</b>
	(b) Write role of pharmacist in the management of adverse drug reactions.	<b>05</b>
	(c) Differentiate between Adverse drug reaction and Adverse event.	<b>05</b>
<b>Q. 6</b>	(a) What are merits and demerits of spontaneous reporting?	<b>06</b>
	(b) Write a note on adverse drug reactions of Liver	<b>05</b>
	(c) Write a note on Dermatological ADRs.	<b>05</b>
<b>Q.7</b>	(a) Write a note on naranjo's causality assessment scale.	<b>06</b>
	(b) Explain spontaneous reporting of adverse drug reactions with suitable examples.	<b>05</b>
	(c) Write mechanism of ADRs with examples.	<b>05</b>

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