

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? **10**
Give sample formats for ADR reports. Describe the role of pharmacist in detection and management of ADRs.
(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**
