

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm - SEMESTER– VII EXAMINATION – SUMMER-2016

Subject Code: 2270010

Date: 13/05/2016

Subject Name: Pharmacovigilance

Time: 2:30 PM to 5:30 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 role of pharmacist in detecting, assessing and managing ADR. **06**
(b) Write a note on WHO international drug monitoring programme. **05**
(c) Describe hematological ADRs with suitable examples. **05**
- Q.2** (a) Describe cohort event monitoring of ADR. **08**
(b) What are medication errors? Describe medication errors with examples. **08**
Discuss role of pharmacist in prevention of medication errors.
- Q.3** (a) Write alphabetic classification of adverse drug reactions. Describe pharmacokinetic mechanisms of type-A adverse drug reactions in detail. **08**
(b) Write type and structure of Individual Case Safety Report (ICSR) as per ICH E2B guidelines. **08**
- Q.4** (a) Compare and contrast between WHO and Naranjo's casualty assessment scale. **10**
(b) Define Signal. Discuss sources and scope of signal detection. **06**
- Q.5** (a) Explain spontaneous reporting of adverse drug reactions with suitable examples. What are merits and demerits of spontaneous reporting? **08**
(b) Enumerate adverse effects of various antibiotics in brief. Discuss super-infection, gray baby syndrome, Fanconi syndrome and red-men syndrome in brief. **08**
- Q.6** (a) i. Explain: Thalidomide tragedy. **06**
ii. Differentiate between Adverse drug reaction and Adverse event.
iii. Explain: Idiosyncrasy.
(b) Explain serious adverse events. How it is managed and reported to regulatory agency? **05**
(c) Write current Pharmacovigilance programme in India. State the benefits in brief. **05**
- Q.7** (a) Write in brief about Phase-IV of clinical trials (Post-marketing surveillance). Discuss need of pharmacovigilance in clinical trials. **06**
(b) What are Spurious, Falsely labelled, Falsified, Counterfeit (SFFC) medicines? **10**
What encourages counterfeiting of medicines? What should be done to ensure the safety, efficacy and quality of medicines?
