

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

## GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph. - SEMESTER- • EXAMINATION – SUMMER-2018

**Subject Code:2270010**

**Date: 01/06/2018**

**Subject Name: Pharmacovigilance**

**Time: 02:30PM TO 05:30PM**

**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) | Write a note on prevention of medication errors                               | 06 |
|      | (b) | Define Signal. Discuss assessment and validation of signal                    | 05 |
|      | (c) | Discuss forms of spontaneous ICSR   | 05 |
| Q.2  | (a) | Define Pharmacovigilance. Discuss various methods of Pharmacovigilance        | 06 |
|      | (b) | Explain the role of ICSR in Pharmacovigilance                                 | 05 |
|      | (c) | How Phase IV clinical trials help in Pharmacovigilance? Explain               | 05 |
| Q.3  | (a) | What is ADR? Describe various types of ADR                                    | 06 |
|      | (b) | Discuss advantages & disadvantages of spontaneous ICSR system                 | 05 |
|      | (c) | Describe content and structure of ICSR  | 05 |
| Q.4  | (a) | Write a detailed note on hematological ADR                                    | 06 |
|      | (b) | Explain Pharmacogenetic causes of ADR with suitable example                   | 05 |
|      | (c) | Write a brief note on Pharmacovigilance regulation in India                   | 05 |
| Q.5  | (a) | What is medication error? Explain types of medication error                   | 06 |
|      | (b) | Enlist ADR of Antiinfective drugs. Explain any two ADR of antiinfective drugs | 05 |
|      | (c) | Discuss the scope of Pharmacovigilance  | 05 |
| Q. 6 | (a) | What is SSFFC? How counterfeiting of medicines can be prevented?              | 06 |
|      | (b) | What is the impact of ADR on public health?                                   | 05 |
|      | (c) | Write a note on Naranjo scale of casualty assessment of ADR                   | 05 |
| Q.7  | (a) | Explain the mechanism of ADR  | 06 |
|      | (b) | Give a brief account on WHO international drug monitoring programme           | 05 |
|      | (c) | Write a note on observational study of Pharmacovigilance in clinical trial    | 05 |

\*\*\*\*\*