

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Ph - SEMESTER– VIII • EXAMINATION – WINTER -2022

Subject Code:BP805TT**Date: 23/12/2022****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.

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| Q.1 | (a) Give the anatomical, therapeutic and chemical classification of drug. | 06 |
| | (b) Discuss the management of ADR. | 05 |
| | (c) Write a short note on pre clinical phase. | 05 |
| Q.2 | (a) Write a short note on Pharmacovigilance Program of India (PvPI). | 06 |
| | (b) Discuss the post approval phase (PMS) | 05 |
| | (c) What is the importance of effective communication in Pharmacovigilance? | 05 |
| Q.3 | (a) Give the definition and classification of ADRs with examples. | 06 |
| | (b) Write a short note on cross sectional studies. | 05 |
| | (c) Discuss the drug safety evaluation in pregnancy and lactation. | 05 |
| Q.4 | (a) Discuss the international classification of diseases. | 06 |
| | (b) Enlist the different types of methods for causality assessment and explain the Naranjo Scale. | 05 |
| | (c) Write a short note on “Schedule Y”. | 05 |
| Q.5 | (a) Discuss the Vaccine Pharmacovigilance in detail. | 06 |
| | (b) Discuss the importance of safety monitoring of medicine. | 05 |
| | (c) Write a short note on WHO drug dictionary. | 05 |
| Q.6 | (a) Discuss the organization and objectives of ICH. | 06 |
| | (b) Write a short note on Contract research organizations (CROs). | 05 |
| | (c) Write a role of Good clinical practice in Pharmacovigilance studies. | 05 |
| Q.7 | (a) Write a note about genetics related ADR with example. | 06 |
| | (b) Discuss the specialized resources for ADRs. | 05 |
| | (c) Explain about adverse events following immunization. | 05 |
