Seat No: _____ **Enrollment No: _____**

PARUL UNIVERSITY

FACULTY OF PHARMACY

B. Pharm., Summer 2023-24 Examination

Semester: 8 **Date: 13/05/2024**

Subject Code: BP805ET **Time: 10:00am to 1:00pm**

Subject Name: Pharmacovigilance **Total Marks: 75**

Instructions:

1. All questions are compulsory.
2. Figures to the right indicate full marks.
3. Make suitable assumptions wherever necessary.
4. Start new question on new page.

Q.1	**Objective type Questions (Answer all the questions)** (2 Mark Each)	**(20)**	**CO**	**PO**	**Bloom's Taxonomy**
1.	Write about CIOMS forms.		**5**	1-4,6-8,11	**2**
2.	Explain drug safety evaluation in pregnancy with example.		**5**	1-4,6-8,11	**3**
3.	Write about international classification of diseases.		**2**	1-4,6-8,10-11	**1**
4.	What is drug event monitoring?		**1**	1-4,6-9,11	**1**
5.	Explain targeted clinical investigation.		**3**	1-4,6-8,11	**3**
6.	What is a daily defined dose?		**2**	1-4,6-8,10-11	**1**
7.	What is pharmacovigilance planning?		**4**	1-4,6-8,11	**1**
8.	Mention few examples of predictable adverse drug reactions.		**1**	1-4,6-9,11	**3**
9.	What is post marketing safety?		**4**	1-4,6-9,11	**1**
10.	Enumerate the drug information resources in pharmacovigilance.		**2**	1-4,6-8,10-11	**1**
Q.2	**Long Answers (Answer 2 out of 3)** (10 Mark Each)	**(20)**			
1.	Classify adverse drug reaction. How will you detect and report ADR along with causality assessment scales?		**1**	1-4,6-9,11	**1,4**
2.	Ilustrate the vaccine safety surveillance along with the different types pharmacovigilance methods used for passive and active surveillance.		**3**	1-4,6-8,11	**1**
3.	Write about the genetics related ADR with examples which focusing Pharmacokinetics parameters.		**5**	11-4,6-8,11	**3**
Q.3	**Short Answers (Answer 7 out of 9)** (5 Mark Each)	**(35)**			
1.	Write about periodic safety update reports.		**4**	1-4,6-8,11	**3**
2.	Explain International classification of diseases.		**2**	1-4,6-8,10-11	**2**
3.	Write compare and contrast of case control and cohort study.		**3**	1-4,6-8,11	**2,3**
4.	Write about D&C act and schedule Y in pharmacovigilance.		**5**	1-4,6-8,11	**2**
5.	Write short note on Standardized MedDRA queries.		**2**	1-4,6-8,10-11	**2**
6.	Explain about adverse events following immunization.		**3**	1-4,6-8,11	**2**
7.	Explain the establishment of drug safety department in industry.		**2**	1-4,6-8,10-11	**2**
8.	Write about Pharmacovigilance Program of India (PvPI).		**1**	1-4,6-9,11	**2**
9	Discuss good clinical practice in Pharmcovigilance studies.		**4**	1-4,6-8,11	**3**