

Paper Id:

Roll No.

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**B PHARM
(SEM VIII) THEORY EXAMINATION 2022-23
PHARMACOVIGILANCE**

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Time: 3 Hours

Total Marks: 75

Note: Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

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1. Attempt all questions in brief.

2 x 10 = 20

- Define the adverse drug reaction.
- Compute the limitations of detecting ADRs in clinical trials.
- Discuss the PSUR. <https://pharmacyindia.co.in/>
- Classify ADRs according to severity.
- List out factors affecting adverse effects of the vaccine.
- What is phase IV of clinical trials?
- What are CIOMS working groups? <https://pharmacyindia.co.in/>
- Discuss the cohort study with example.
- Discuss the Defined daily doses.
- Illustrate the importance of Pharmacogenomics.

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SECTION B

2. Attempt any two parts of the following:

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10 x 2 = 20

- Differentiate between adverse drug reactions and adverse events with suitable examples. Explain the mechanisms of Type-A and Type-B ADRs.
- Illustrate the vaccine safety surveillance along with the different types of pharmacovigilance methods used for passive and active surveillance.
- Explain the drug safety evaluation in pediatrics and geriatrics.

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SECTION C

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3. Attempt any five parts of the following:

7 x 5 = 35

- Characterize the different methods of causality and severity assessment of ADRs and explain Naranjo's scale.
- Demonstrate the prerequisite for setting up a pharmacovigilance center in a CRO and hospital. <https://pharmacyindia.co.in/>
- Define vaccine. Explain reasons for vaccination failure.
- Summarize the ATC classification of drugs with example.
- Explore the Pre- marketing and Post-marketing clinical trials.
- Illustrate the organization and objectives of ICH. <https://pharmacyindia.co.in/>
- Explain the Schedule Y of Drugs and Cosmetics Act in brief.