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#### **B PHARM**

# (SEM VIII) THEORY EXAMINATION 2022-23

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PHARMACOVIGILANCE

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.

 $2 \times 10 = 20$ 

- (a) Define the adverse drug reaction.
  - (b) Compute the limitations of detecting ADRs in clinical trials.
- (c) Discuss the PSUR. https://pharmacyindia.co.in/
- (d) Classify ADRs according to severity.
- (e) List out factors affecting adverse effects of the vaccine.
- (f) What is phase IV of clinical trials?

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- (g) What are CIOMS working groups?
- (h) Discuss the cohort study with example.
- (i) Discuss the Defined daily doses.
- (i) Illustrate the importance of Pharmacogenomics

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### **SECTION B**

## 2. Attempt any two parts of the following:

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 $10 \times 2 = 20$ 

- (a) Differentiate between adverse drug reactions and adverse events with suitable examples. Explain the mechanisms of Type-A and Type-B ADRs.
- (b) Illustrate the vaccine safety surveillance along with the different types of pharmacovigilance methods used for passive and active surveillance.
- (c) 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:

 $7 \times 5 = 35$ 

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

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