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

Time: 3 Hours ***Total Marks: 75***

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

SECTION A

1. Attempt *all* questions in brief. 2 x 10 = 20

(a) Define the adverse drug reaction.

(b) Compute the limitations of detecting ADRs in clinical trials.

(c) Discuss the PSUR.

(d) Classify ADRs according to severity.

(e) List out factors affecting adverse effects of the vaccine.

(f) What is phase IV of clinical trials?

(g) What are CIOMS working groups?

(h) Discuss the cohort study with example.

(i) Discuss the Defined daily doses.

(j) Illustrate the importance of Pharmacogenomics.

SECTION B

2. Attempt any *two* parts of the following: 10 x 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.

SECTION C

3. Attempt any *five* parts of the following: 7 x 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.

(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.

(g) Explain the Schedule Y of Drugs and Cosmetics Act in brief.

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