R13

Code: 13R00707

B.Pharm IV Year I Semester (R13) Regular Examinations November 2016

PHARMACOVIGILANCE

Time: 3 hours Max. Marks: 70

PART – A

(Compulsory Question)

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1 Answer the following: (10 X 02 = 20 Marks)

(a) Define the term, “Adverse drug reaction”.
(b) What are the types of ADR?
(c) List down the various methods of reporting ADR.
(d) What is causality authorized in ADR monitoring?
(e) Which is the WHO authorized pharmacovigilance center to collate ADRs globally?
(f) Differentiate adverse drug reactions & adverse drug events.
(g) Write note on stimulated reporting.
(h) List down the information resources in pharmacovigilance.
(i) What is a cohort study?
(j) List down the roles of industry in pharmacovigilance monitoring.

PART – B

(Answer all five units, 5 X 10 = 50 Marks)

UNIT - I

2 Explain the WHO international drug monitoring programme.

OR

3 Discuss the importance of drug safety through pharmacovigilance program of India.

UNIT - II

4 Describe the establishment of pharmacovigilance department in hospital.

OR

5 Discuss the various roles & responsibilities of CROs in establishing pharmacovigilance programme.

UNIT - III

6 Explain the importance of passive surveillance in pharmacovigilance.

OR

7 Discuss the various comparative observational studies in pharmacovigilance.

UNIT - IV

8 Describe the guidelines for reporting ADRs in biomedical literature.

OR

9 Discuss the spontaneous case reporting system & its significance in ADR monitoring.

UNIT - V

10 Explain the importance of communication in drug safety crisis management.

OR

11 Discuss the significance of communication with healthcare professionals in pharmacovigilance.

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