Code: 13R00707

R13

B.Pharm IV Year I Semester (R13) Regular & Supplementary Examinations November 2017

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) What is PvPI?
(b) What is causality assessment?
(c) Who monitors ADR globally?
(d) Mention the types of SOPs.
(e) What is passive surveillance?
(f) What is a case-control study?
(g) Define the term spontaneous reporting.
(h) List down the various ADR reporting systems.
(i) Mention the methods of communication in pharmacovigilance.
(j) List the people to whom communication is required in pharmacovigilance.

PART – B

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

UNIT – I

2 Discuss the WHO's international drug monitoring programme.

OR

3 Discuss the importance of drug safety monitoring in India.

UNIT – II

4 Explain any five terminologies used in pharmacovigilance.

OR

5 Discuss the role and responsibilities of CROs in pharmacovigilance.

UNIT – III

6 Discuss the various active surveillance methods.

OR

7 Explain the cross-sectional and case control study in ADR monitoring.

UNIT – IV

8 Discuss the spontaneous reporting system in pharmacovigilance.

OR

9 Describe the guidelines for reporting ADR's in biomedical literature.

UNIT – V

10 Describe the communication in pharmacovigilance and its importance in drug safety crisis management.

OR

11 Explain the communication in pharmacovigilance with regulatory agencies and other health care professionals.

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