

Code: 13R00707

B.Pharm IV Year II Semester (R13) Regular & Supplementary Examinations April 2018

PHARMACOVIGILANCE

Time: 3 hours

Max. Marks: 70

PART – A
(Compulsory Question)

- 1 Answer the following: (10 X 02 = 20 Marks)
- (a) Write down the WHO's definition of, "Adverse Drug Reactions".
 - (b) What is signal detection in pharmacovigilance?
 - (c) List down the types of ADRs with suitable examples.
 - (d) Write a note on Naranjo Scale in assessing an ADR.
 - (e) Who is responsible to collect & collate ADR reports in India?
 - (f) Name various methods of monitoring ADR.
 - (g) Differentiate the term "ADR" & "ADE".
 - (h) What is causality assessment in ADR monitoring?
 - (i) What is dechallenging and rechallenging of drugs in ADR detection?
 - (j) What are Sentinel sites?

PART – B
(Answer all five units, 5 X 10 = 50 Marks)**UNIT – I**

- 2 Discuss the WHO's international drug monitoring programme and the role of pharmacists in monitoring adverse drug reactions.

OR

- 3 Describe the pharmacovigilance program of India and its role in drug safety.

UNIT – II

- 4 Discuss various information resources in pharmacovigilance.

OR

- 5 Discuss about the establishment and operation of drug safety department in industry.

UNIT – III

- 6 Discuss various active surveillance methods in ADR monitoring.

OR

- 7 Discuss various comparative observational studies in monitoring.

UNIT – IV

- 8 Discuss guidelines for reporting ADRs in biomedical literature.

OR

- 9 Describe various reporting systems of ADRs to regulatory authorities.

UNIT – V

- 10 Describe the importance of communication with health care professional in pharmacovigilance.

OR

- 11 Explain the role of communication in pharmacovigilance during drug safety crisis management.
