Final Year **B.Pharm. Sem VIII (CBCS -2015 Course) SUMMER-2019**

SUBJECT: Elective – 1) Pharmacovigilance and Medicine Safety

Day : Wednesday Time : 2:00 P.M. TO 5:00 PM.

Date : 08-05-2019 S-2019-4417 Max Marks : 60

N.B.:

1) Q. No.1 and Q.No.5 are **COMPULSORY**. Out of the remaining questions attempt **ANY TWO** questions from each section.
2) Answer to both the sections should be written in **SEPARATE**
3) Figures to the rights indicate **FULL** marks

SECTION -I

Q.1 Solve any **Five.** **(10)**

- **a.** Define Pharmacovigilance.
- **b.** Define adverse drug reaction.
- **c.** What is observational study?
- **d.** What is passive surveillance?
- **e.** What are case series?
- **f.** What are the limitations of clinical trials?

Q.2
- **a.** Explain the role of registries in monitoring of drug safety. **(05)**
- **b.** Explain the scope and objectives of Pharmacovigilance programme of India. **(05)**

Q.3 Explain in detail the various drug information resources along with advantages and disadvantages. **(10)**

Q.4 Write short note on any **Two.** **(10)**

- **a.** Suspected adverse drug reaction reporting form.
- **b.** Case control and cohort study.
- **c.** Causality assessment of adverse drug reaction.

SECTION -II

Q.5 Solve any **Five.** **(10)**

- **a.** What is medication error?
- **b.** What is science of safety?
- **c.** Classify medication errors.
- **d.** What is spontaneous reporting system?
- **e.** What is safety update report?
- **f.** What is meta-analysis?

Q.6
- **a.** Write a note on disclosure of adverse event. **(05)**
- **b.** Write a note on signal detection. **(05)**

Q.7 Explain the measures to prevent the medication errors. **(10)**

Q.8 Write short note on any **Two.** **(10)**

- **a.** Risk management.
- **b.** Medication error reporting form.
- **c.** Actions taken from the Pharmacovigilance findings.

* * * * *