



AJEENKYA

D Y PATIL UNIVERSITY

End Term Examination (December 2019)

School: SOM

Program: MSc CLINICAL RESEARCH

Course: PHARMACOVIGILANCE II

Course Code: MGT690

Semester: 3rd

Max Marks: 50 marks

Duration (mins): 150 mins

Instructions to the students

- 1) **The Question paper consists of two sections - Section I and Section II.**
- 2) **All questions are compulsory.**
- 3) **Neat flow charts or diagrams must be drawn wherever necessary**
- 4) **Figures on the right indicate full marks**

SECTION 1

Q 1) Answer the following:

[2x5=10]

- a) Explain spontaneous reporting. What are the merits and the demerits of spontaneous reporting?
- b) Describe solicited and unsolicited sources of ICSR.
- c) When do we consider an event to be serious? What are the minimum criteria required for a valid case?
- d) Current methods of Pharmacovigilance and its significance.
- e) What are epidemiology studies?

Q 2) Attempt any two of the following:

[5x2=10]

- a) Explain about the various roles and responsibilities of Pharmacovigilance.
- b) Describe the national Pharmacovigilance programme of India.
- c) What is pharmacogenetics? What are its applications?
- d) Explain prescription event monitoring.

Q 3) Attempt any one of the following: [5x1=5]

- a) Describe post-marketing surveillance (PMS) in relation to- Definition, sources of PMS information and benefits of PMS system. Also explain the limitations of pre-marketing services.
- b) Explain hospital based surveillance with a suitable example.

SECTION II

Q 1) Answer the following: [2x5=10]

- a) Hepatic enzymes involved in drug metabolism.
- b) What is baseline and baseline examination?
- c) What are the factors affecting adverse drug reactions.
- d) Explain about WHO Pharmacovigilance Programme for Global monitoring.
- e) Explain the hierarchy In MedDRA.

Q 2) Attempt any two of the following: [5x2=10]

- a) Elaborate pharmacovigilance of herbal drugs.
- b) Explain pharmacovigilance regulations in Canada.
- c) Give the mechanism of Type- A reactions.
- d) Explain additive effect with serotonin as an example. Also add a note on the functions of the following drugs- Sertraline, carbamazepine, ritonavir

Q 3) Attempt any one of the following: [5x1=5]

- a) Types, detection, reporting system and management of Adverse Drug Reactions (ADR).
- b) Explain about MedDRA in detail.

***** ALL THE BEST *****