

Rajiv Gandhi University of Health Sciences

IV Semester M.Sc. [Clinical Research] Degree Examination – OCT-2019

[Time: 3 Hours]

[Max. Marks: 50]

PAPER IV: PHARMACOVIGILANCE

Section B

Q.P. CODE : 9698

Your answers should be specific to the questions asked.

Draw neat labeled diagrams wherever necessary. Answer all questions

(Note : Both QP Codes 9697 and 9698 are to be answered within total duration of 3 hours)

(Use separate answer booklets for section A and section B)

LONG ESSAY

1 X 20 = 20 Marks

1. What is an ICSR? Discuss its sources, assessment and reporting requirements according to ICH. Add a note on Safety Signal.

SHORT ESSAY

2 X 10 = 20 Marks

2. Write a note on post marketing surveillance. Add a note on methods of surveillance.
3. Differentiate the following –
AE-SAE
AE-ADR
ICSR-PSUR
RMP-GMP
GCP-GLP

SHORT NOTES

2 X 05 = 10 Marks

4. Write a note on the pharmacovigilance obligations of pharmaceutical companies.
5. Describe the important factors considered for causality assessment.

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