

**Rajiv Gandhi University of Health Sciences**  
**IV Semester M.Sc. [Clinical Research] Degree Examination – OCT-2019**

**[Time: 3 Hours]**

**[Max. Marks: 50]**

**REGULATORY AFFAIRS**

**PAPER IV**

**Section A**

**Q.P. CODE : 9697**

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. Write a note on Global Pharmaceutical Developments and Regulations. Add a note on role of marketing authorization holders in handling drug safety for a medicinal products.

**SHORT ESSAY**

**2 X 10 = 20 Marks**

2. Write a note on Over the counter (OTC) drugs, Ayurvedic and Homoeopathy drugs and their safety regulation.
3. Write about Ethics in clinical trials and Pharmacovigilance.

**SHORT NOTES**

**2 X 05 = 10 Marks**

4. Write a note on Quality compliance in safety reporting.
5. Regulatory inspection.

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