Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - JUNE-2019

[Time: 3 Hours] **[Max. Marks: 75]**

Regulatory Affair

Q.P. CODE: 5130

Your answers should be specific to the questions asked.
Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Explain drug regulatory issues related to the generic products.
2. Explain regulatory framework for good clinical practices in European Union.
3. Explain the regulatory requirements for CRO.
4. Define DMF. Explain different types of DMFs.

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Define Orange Book. Explain the salient features and scope of Orange book.
6. Explain regulatory framework for approval of medical devices in India.
7. Describe the general principles of safety monitoring in clinical trials.
8. Explain ICH-Q8
9. Explain the stages of ANDA process.
10. Explain IMPD.
11. Explain IRB.
12. What is CTD? Explain the objectives and benefits of CTD.
13. Explain the regulatory requirements in TGA.
14. Write a note on HIPPA.

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