Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - MAY-2018

[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. Write salient features of Hatch Waxman act and write note on orange book.
2. Explain briefly USFDA regulatory requirements for NDA product approval.
3. Explain ICH Q8, Q9 and Q10.
4. Discuss the in vitro drug product performance of USFDA.

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

5. Salient feature of EU guidelines
6. Importance of Health insurance portability and accountability act
7. General principles in safety monitoring in clinical trials.
8. Explain the procedure for Inform consent in clinical trials.
9. Which are ROW countries?
10. Duties and responsibilities of Institutional review board
11. Post approval regulations of MHRA
12. Explain ICH Q10.
13. General guidelines of out sourcing BA and BE to CRO
14. What are set of safety guideline of ICH?

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