Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - Dec-2017

[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 documentation in Pharmaceutical industry with respect to Drug master file and distribution records.
2. Explain pharmacovigilance safety monitoring in clinical trials.
3. Give details about CMC post approval regulatory affairs.
4. Explain regulatory requirements and process of ANDA.

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

5. Explain regulatory requirement in MHRA.
6. Explain the stages of NDA process.
7. Write a note on health Insurance Portability and accountability Act.
8. Discuss Clinical trials in informed consent process.
9. What is eCTD? Explain the advantages of electronic submission.
10. Composition of Institutional Review Board (IRB). Roles and Responsibilities of the investigators.
11. Give details about the ICH guidelines for safety.
12. Explain Hatch- Waxman Act.
13. Write detail about outsourcing of BA and BE to CRO.
14. Write about regulatory guidance for approval process for Biological products.

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