Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - JAN-2019

Time: Three Hours **Max. Marks: 75 Marks**

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. Discuss Regulatory requirement of NDA approval process.
2. Explain the significance of documentation in BA-BE studies and add a note on outsourcing BA and BE to CRO.
3. Describe the regulatory guidelines for the approval of medical devices.
4. Write in detail about clinical trials and its importance in product approval process.

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

5. What is the significance of Hatch – Waxman Act?
6. Describe the working procedures of institutional review board.
7. Discuss ICH guidelines on efficacy.
8. Write a detailed note on Drug Master File.
9. Explain the regulatory requirements of TGA.
10. Give the details about IMPD.
11. Write a note on Scale up process approval changes.
12. Give regulatory requirements for investigational new drug submission, format and content of IND in non clinical drug development.
13. Discuss about CTD and ETCD format and its usefulness in regulatory affairs.
14. Write a note on HIPAA.

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