Rajiv Gandhi University of Health Sciences, Karnataka

First Semester M. Pharm Degree Examination - 26-Jul-2022

[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.

Answer All The Questions **10 x 7.5 = 75 Marks**

1. Outline about Investigation Medicinal Products Dossier (IMPD) and Investigational Brochure in non clinical drug development process.
2. Explain in detail New Drug Application (NDA) Regulatory approval Process.
3. Explain about Clinical trials requirements for approvals for conducting clinical trials.
4. Elaborate the regulatory guidance and guidelines for filing and approval process for Biologics in US.
5. Discuss about Post marketing Surveillance.
6. Explain about Outsourcing BA to CRO.
7. What is Drug Master File (DMF) and write the different types of DMF.
8. What is Hatch-Waxman act? What are the patent certifications under Hatch-Waxman act?
9. **Explain the HIPAA in detail.**
10. Explain ICH guidelines of efficacy.

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