Rajiv Gandhi University of Health Sciences, Karnataka

First Semester M. Pharm Degree Examination - 25-Mar-2021

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.

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

1. Describe Hatch Waxman act.
2. Discuss regulatory guidelines for filing and approval process for API.
3. Discuss the Submission of global documents in CTD/ECTD formats.
4. Describe the process of developing clinical trial protocol.
5. Describe the working procedures of institutional review board.
6. Explain guidelines of ICH safety.
7. Discuss the significance of documentation in pharmaceutical industry.
8. Give regulatory requirements for content of IMPD.
9. Explain the pharmacovigilance safety monitoring in clinical trials.
10. Describe in detail NDA regulatory approval process.

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