Rajiv Gandhi University of Health Sciences, Karnataka

First Semester M. Pharm Degree Examination - 14-Dec-2020

[Time: 3 Hours] **[Max. Marks: 75]**

REGULATORY AFFAIRS
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. Write a note on drug master file and its different types Master Formula Record.
2. Explain regulatory guidance and guidelines for filing and approval process for API.
3. Discuss the submission of global documents in CTD/eCTD formats.
4. Elaborate the Pharmacovigilence safety monitoring in clinical trials
5. Discuss the process of NDA.
6. Explain in detail ANDA regulatory approval process.
7. Explain the regulatory requirements of EU.
8. Explain the regulatory requirements of MHRA.
9. Explain the preparation of Dossiers and their submission to regulatory agencies in different countries.
10. Discuss about clinical trials in informed consent process and procedures.

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