Rajiv Gandhi University of Health Sciences, Karnataka

First Semester M. Pharm Degree Examination - 17-Nov-2021

[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. Explain the process of approval of generic drug products.
2. Write the good clinical practices for clinical research in India.
3. Write the WHO guidelines on stability testing API's.
4. Describe in detail about CMC post approval regulatory affairs.
5. Write MHRA guidelines.
6. Write the functions of USFDA guidelines.
7. Explain salient features of Hatch-Waxman Act.
8. Explain the stages of NDA process.
9. Describe briefly regulatory guidelines for approval process for novel therapies.
10. Write briefly about Pharmacovigilence safety monitoring in Clinical trials.

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