Rajiv Gandhi University of Health Sciences, Karnataka

First Semester M. Pharm Degree Examination - 23-Nov-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. Describe the NDA Regulatory approval Process.
2. Explain about Good Manufacturing Practice for finished Pharmaceuticals.
3. Explain in detail ICH guidelines of safety.
4. Give the regulatory requirements of Investigational New Drug Submission.
5. Explain briefly ANDA Regulatory approval process.
6. Explain overview about the MHRA Regulatory requirements.
7. Summarize about the Drug Master File (DMF) and write the different types of DMF.
8. Discuss briefly the submission of global documents in CTD/eCTD formats.
9. Write a note on *In-vitro* drug product performance.
10. Explain the Regulatory requirements to clinical study process.

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