Rajiv Gandhi University of Health Sciences, Karnataka

First Semester M. Pharm Degree Examination - 16-May-2025

[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 overview about the MHRA Regulatory requirements.
2. Explain briefly NDA Regulatory approval process.
3. Elaborate the preparation of Dossiers and their submission to regulatory agencies in different countries.
4. Discuss in detail Regulatory requirements of EU.
5. Write briefly about overview of ICH safety guidelines.
6. Describe about CMC regulatory compliance for pharmaceuticals.
7. Describe regulations of drug approval in US.
8. What is Drug Master File (DMF) and write the different types of DMF.
9. Discuss the submission of global documents in CTD/eCTD formats.
10. Explain brief about HIPAA-new, requirement to clinical study process.

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