Rajiv Gandhi University of Health Sciences, Karnataka

First Semester M. Pharm Degree Examination - 10-Nov-2023

[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. Discuss the TGA guideline for drug products.
2. Explain the investigational medicinal products dossier.
3. Write the general procedure for NDA submission to USFDA.
4. Discuss the master formula record.
5. Write the general procedure for ANDA submission to USFDA.
6. General guidelines for application for biological products
7. Explain the ICH quality guidelines.
8. Elaborate on investigator brochure
9. Brief note on SUPAC.
10. **Discuss development of clinical trial protocol and add a note on informed consent in clinical trial.**

* * * * *