Rajiv Gandhi University of Health Sciences, Karnataka

First Semester M. Pharm Degree Examination - 07-Jun-2024

[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 significance of documentation in BE studies and add a note on outsourcing BE to CRO.
2. Describe regulatory requirements for IND submission. Write the format and contents of IND.
3. Write the components of Clinical trial protocol. Explain Inclusion and Exclusion criteria using a hypothetical case of a clinical trial.
4. Explain ICH guidelines for safety.
5. Discuss briefly *In-vitro* drug product performance.
6. Explain the process of post marketing surveillance.
7. Explain briefly the regulatory requirements for registration of API's in US.
8. Define CTD and eCTD. Write the structure of CTD and diagrammatic representation of CTD.
9. What is investigator brochure? Write the contents and purpose of investigators brochure.
10. Write a note on regulatory requirement for MHRA.

* * * * *