# Rajiv Gandhi University of Health Sciences, Karnataka

**First Semester M. Pharm Degree Examination - 05-Jun-2023**

**[Time: 3 Hours]** **[Max. Marks: 75]**

## REGULATORY AFFAIRS
## 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. Regulatory requirements product approval for obtaining ANDA.
2. Describe in detail Hatch-Waxman act.
3. Discuss the submission of global documents in CTD/eCTD formats.
4. Explain in detail about institutional review board/independent ethics committee.
5. Write in detail outsourcing BE to CRO.
6. What is a DMF? Explain in detail.
7. Explain regulatory guidance and guidelines for filing and approval process for API.
8. Explain in detail about MHRA.
9. Give details about the ICH guidelines for quality of products.
10. Describe the requirement to clinical study process.

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