Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 24-Nov-2022

Time: Three Hours **Max. Marks: 75 Marks**

PHARMACEUTICAL REGULATORY SCIENCE
Q.P. CODE: 5036

Your answers should be specific to the questions asked
Draw neat labeled diagrams wherever necessary
All the Questions are compulsory

LONG ESSAYS **2 x 10 = 20 Marks**

1. Explain the stages in development of new drug.
   OR
   What is CTD and eCTD? Explain the different modules of CTD in detail.

2. Discuss the application and approval process for ANDA.

SHORT ESSAYS **7 x 5 = 35 Marks**

3. Explain the organization structure and functions of Australian drug regulatory body.
   OR
   Explain code of federal regulation.

4. Write briefly on the development of clinical trial protocol.
   OR
   Explain the salient features of orange book.

5. Explain the formation and functions of independent ethics committee.
6. What is DMF? Explain the contents of DMF.
7. Explain organization structure and functions of drug regulatory authority of Japan.
8. Explain the ethical principles of informed consent form for clinical trial process.
9. Concept of generic drug product development.

SHORT ANSWERS **10 x 2 = 20 Marks**

10. Generic vs Innovator.
11. Phase II clinical trials.
12. Modules of ASEAN common technical document.
13. Organogram of EU regulatory authority.
14. Safety monitoring in clinical trials.
15. Mention changes to an approved NDA/ANDA.
16. Define the term USFDA and EMDA.
17. Pre-clinical studies.
18. Salient features of purple book.
19. Define the term IND and NDA.

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