Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 10-Nov-2023

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 application and approval process of IND.

   OR

   Explain different stages involved in development of new drugs.

2. Explain different modules of DMF. Discuss the open and closed parts of DMF.

SHORT ESSAYS

7 x 5 = 35 Marks

3. Define and differentiate CTD and eCTD.

   OR

   Explain the Phase II clinical trials.

4. Explain non-clinical studies.

   OR

   Explain the changes to an approved NDA/ANDA.

5. Explain the importance of 21 CFR. Discuss 21 CFR Part 210 & 211.
6. Discuss modules of ACTD.
7. Explain the inclusion and exclusion criteria in clinical trials.
8. Discuss the importance of pharmaceutical regulatory affairs in industry.
9. Explain the safety monitoring in clinical trials.

SHORT ANSWERS

10 x 2 = 20 Marks

10. Functions of Japan drug regulatory authority.
11. Importance of DMF.
12. Pre-clinical studies.
13. Explain concept of generic.
14. Functions of EU regulatory authority.
15. Non – eCTD submission form.
16. Informed consent form.
17. Purple book.
18. Constitution of IRB.
19. Module III in eCTD.

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