Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 07-Jul-2022

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

PHARMACEUTICAL REGULATORY SCIENCES

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. What is innovator and generic products? Explain stage in development of generic formulations. – unit 1

   OR

   Define CTD and discuss the process involved in its submission.

2. Explain the organization and functions of regulatory bodies of EU and Australia. – unit - 2

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

3. Explain code for federal regulation with respect to Part 21.

   OR

   What is CTD and eCTD? Differentiate them.

4. Explain inclusion and exclusion in clinical trials. – unit - 1

   OR

   Explain changes made to approved NDA. – unit - 2

5. Explain salient features of orange book.
6. Discuss the criteria for selection of human volunteers in clinical trials. – unit 4
7. Explain the development of clinical trial protocols. – unit -4
8. Explain different stages in non-clinical studies. – unit 1
9. Explain the application and approval process for IND. – unit - 2

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

10. Functions of Japan drug regulatory body. – unit 2
11. Salient features of DMF.
12. Phase II clinical trials. – unit 1
13. Export of generic products. – unit -1
14. Institutional Review Board.
15. Safety monitoring in clinical trials.
16. Open parts of DMF.
17. Objectives of regulatory affairs.
18. Differentiate innovator and generic products. – unit 1
19. Functions of US FDA. – unit - 2

******