Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 19-Nov-2021

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. Discuss different stages of pre-clinical studies. – unit - 1
   OR
   Discuss the application and approval process of ANDA. – unit 2
2. Discuss the procedure for the export of the pharmaceutical products.

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

3. Explain CTD and eCTD.
   OR
   Explain inclusion and exclusion in clinical trials.
4. Explain code for federal regulation with respect to Part 21.
   OR
   Explain changes made to approved NDA. – unit - 2
5. Explain salient features of purple book.
6. Explain the organization and functions of CDSCO.
7. Explain briefly generic product development process. – unit - 1
8. Explain the formation and functions of institutional review board.
9. Briefly write a note on submission of DMF.

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

10. Objectives of regulatory affairs department in pharma industry.
11. Enlist the types of DMF.
12. Non-clinical studies.
13. Pharmacovigilance.
14. Differentiate innovator and generic products.
15. Modules in ACTD.
16. Functions of US FDA.
17. What is clinical trial protocol?
18. Write a note on IND.
19. Orange book

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