Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 10-Jun-2024

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 regulatory approval process for IND.
   OR
   Discuss the organisation structure, hierarchy and functions of USFDA.
2. Explain the different modules of CTD in detail.

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

3. Explain the organization structure and functions of Japan drug regulatory body.
   OR
   Explain the stages of drug discovery process.
4. Discuss the importance of orange book in development of generic product.
   OR
   Explain the application and approval of ANDA.
5. Write briefly on clinical trial protocol.
6. Explain the salient features of pharmacovigilance.
7. Explain non-clinical activities in drug development.
8. Explain changes to an approved NDA/ANDA.
9. Write an overview on ACTD.

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

10. Enlist the functions of Europe drug regulatory authority.
11. What is DMF? Enlist the types.
12. Differentiate NDA and ANDA.
13. Enlist the different applications used for approval in USFDA.
14. Role of regulatory affairs personnel in pharmaceutical industry.
15. Briefly write on Phase I studies.
16. Importance of purple book.
17. Informed consent form.
18. Mention the general list of 21 CFR.
19. Non-clinical trials.

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