# Rajiv Gandhi University of Health Sciences, Karnataka

**VIII Semester B. Pharm Degree Examination – 04-Nov-2024**

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

## 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. Discuss the various stages involved in generic product development
   **OR**
   Discuss the application and approval process of ANDA
2. Define CTD and discuss the process involved in its submission

### SHORT ESSAYS

**7 x 5 = 35 Marks**

3. Differentiate innovator and generic products
   **OR**
   Discuss organization structure and functions of regulatory authority for EU
4. Explain organization structure and functions of USFDA
   **OR**
   Define and explain the modules of eCTD
5. Write a note on overview of DMF
6. Explain the salient features of pharmacovigilance
7. Discuss the criteria for selection of human volunteers in clinical trials
8. Explain the salient features of orange book
9. Explain the formation and functions of independent ethics committee

### SHORT ANSWERS

**10 x 2 = 20 Marks**

10. Define pre-clinical studies
11. Define the term IND and NDA
12. Write the functions of CDSCO
13. Concept of generics
14. Write a note on technical documentation
15. Modules in ACTD
16. What is clinical trial protocol?
17. Define institutional review board
18. Define GCP and its importance
19. What is federal register?

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