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Rajiv Gandhi University of Health Sciences, Karnataka
VII Semester B. Pharm Degree Examination – 30-May-2024

Time: Three Hours

Max. Marks: 75 Marks

INDUSTRIAL PHARMACY - II

Q.P. CODE: 5030

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 protocol for pilot plant scale up for tablets production.

OR

Discuss the Granularity of TT Process for Active Pharmaceutical Ingredients (API) and excipients.

2. Explicit the data's to be submitted during New Drug Application (NDA) filing.

SHORT ESSAYS

7 x 5 = 35 Marks

3. Discuss the Significance of personnel requirements in pilot plant scale up.

OR

Discuss the Documentation process involved in TT.

4. Differentiate between qualification and validation with suitable examples.

OR

Discuss the Types of studies involved in Pre-clinical Drug Development.

5. Write a note on ICH E6 (R2) Good Clinical Practice guidelines.
6. Write a note on QbD concept as per ICH Q8 Guidelines.
7. Write a note ISO 14000 Guidelines.
8. Write a note on Drug Technical Advisory Board (DTAB) and its functions.
9. Discuss new drugs approval process in India.

SHORT ANSWERS

10 x 2 = 20 Marks

10. What are the different parts of batch manufacturing record?
11. What is platform technology?
12. Write any two reasons for technology transfer in Pharmaceutical Industry.
13. Write the functions of BCIL.
14. List out various Regulatory Authorities.
15. Enlist the key elements in managing clinical programs.
16. Write the four reasons for disqualification of testing facilities.
17. Classify Changes and give examples.
18. What is CTD?
19. Differentiate the assignable and non-assignable causes as per OOS.
