Rajiv Gandhi University of Health Sciences, Karnataka

VII Semester B. Pharm Degree Examination – 04-Nov-2023

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

2 x 10 = 20 Marks

LONG ESSAYS

1. Give Regulatory Requirements for INDA approval process.

   OR

   Explain the concepts of Total Quality Management and Quality by Design (QbD).

2. Explain the objectives and functions CDSCO and COPP.

7 x 5 = 35 Marks

SHORT ESSAYS

3. Write a note on scale up process approval changes.

   OR

   Give the details about Quality Risk Management.

4. Discuss the Technology Transfer agencies in India.

   OR

   Explain the significance of documentation in BA – BE studies.

5. Write in detail about Pilot plant scale up considerations for solids.
6. Write a note on documentation of finished products and packaging materials.
7. What is clinical research protocols and data presentation?
8. Write the elements of ISO14000.
9. Discuss the significance of GMP.

10 x 2 = 20 Marks

SHORT ANSWERS

10. Write the significance of personnel requirements in pharma industry.
11. Write the guidelines for technology transfer (TT).
12. Write the functions of clinical studies.
13. What is State licensing authority?
14. What are the objectives of NRDC?
15. What are MoUs and confidential agreement?
16. Define qualification and validation.
17. Discuss the Role of Regulatory affairs department.
18. What is six sigma concept and OOS?
19. Enlist salient features of ISO 9000.

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