Rajiv Gandhi University of Health Sciences, Karnataka

VII Semester B. Pharm Degree Examination – 31-May-2023

Max. Marks: 75 Marks

Time: Three Hours

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. Explain how master formula records and batch manufacturing records are developed in pilot plant scale up studies.

OR

Discuss quality risk management studies as per ICHQ9 guideline.

2. Discuss the Role of regulatory affairs department in pharma industry.

7 x 5 = 35 Marks

SHORT ESSAYS

3. What is a pilot plant? What is the significance of Pilot Plant scale up techniques?

OR

What are the Barriers of Technology Transfer?

4. Discuss the TT Process of packaging materials.

OR

Explain the Different Phases of drug development.

5. Describe the key elements in managing clinical programs.
6. What are the advantages of Implementing TQM?
7. What is the Benefits of NABL accreditation?
8. Write a note on Central Drugs Testing Laboratories (CDTL).
9. Describe the Organization of CDSCO with flow diagram.

10 x 2 = 20 Marks

SHORT ANSWERS

10. Enlist the significances of batch formula record.
11. How equipment are categorized as per SUPAC guideline
12. Write the two importance of Technology Transfer in Pharmaceutical Industry.
13. Write the primary objectives NRDC.
14. Write two key elements in managing clinical programs.
15. Write the significance BE study.
16. What is zero-defect product?
17. What are the objectives of GLP?
18. Two functions of Port Offices of CDSCO
19. Write the types of drugs for which COPPs may be issued.

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