21P1165

Rajiv Gandhi University of Health Sciences, Karnataka

VII Semester B. Pharm Degree Examination – 28-Apr-2025

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

   OR

   Write a note on WHO guidelines for technology transfer.

2. Discuss regulatory requirements NDA approval process.

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

3. What is pilot plant? What are the significances of pilot plant scale up techniques?

   OR

   Write a note on process validation.

4. Discuss the granularity of technology transfer process for API.

   OR

   Explain the historical overview of regulatory affairs.

5. Explain the significance of documentation in BA-BE studies.
6. Write a note on ISO 14000 guidelines.
7. Explain six sigma concepts for quality improvement.
8. Describe the organization of CDSCO with flow diagram.
9. Write a note on drug approval for new drugs 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. What are the steps involved in technology transfer?
13. What are the objectives of NRDC?
14. Define biostatistics.
15. Define clinical trials and write its importance.
16. What are the advantages of implementing TQM?
17. What are the benefits of ISO 9000?
18. Write any four regulatory requirements of approval for new drugs.
19. List out the places of zonal and sub zonal offices of CDSCO.

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