

Rajiv Gandhi University of Health Sciences, Karnataka

VII Semester B. Pharm Degree Examination – 17-Nov-2022

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 various general requirements for setting up a pilot plant for pharmaceutical preparation.

OR

Discuss the stages involved in technology transfer in pharmaceutical industry.

2. Discuss general consideration of investigational New drug application.

SHORT ESSAYS

7 x 5 = 35 Marks

1. Discuss the importance of platform technology.

OR

How analytical methods are exchanged in a technology transfer.

4. Explain technology transfer sample protocol in pharmaceuticals.

OR

Write a note on drug development team and their functions.

5. Discuss the different phases of clinical trials.
6. Discuss the objectives and scope of GLP in pharmaceutical industry.
7. Describe the procedure for NABL accreditation.
8. Discuss the scope and objectives of COPP (Certificate of Pharmaceutical Product).
9. Write the functions of Drug Controller General of India (DCGI).

SHORT ANSWERS

10 x 2 = 20 Marks

10. What is the difference between pilot scale and scale up?
1. What is SUPAC?
12. What do you mean by Sending Unit and Receiving Unit
13. What is Operational Qualification (OQ) and Performance Qualification (PQ)
14. What is a regulatory affair? What are its Goals?
15. What are BA-BE studies? What is the need of BA-BE studies?
16. Two advantages of implementing TQM.
17. Enlist the benefits of ISO 14000.
18. Two functions of Drugs technical advisory board (DTAB).
19. What is common technical document (CTD)?
