

Rajiv Gandhi University of Health Sciences, Karnataka

VII Semester B. Pharm Degree Examination – 15-Jun-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 in detail about the significance of pilot-plant scale up study and large scale manufacturing techniques of Liquid orals.
OR
2. Discuss technology transfer from R and D to production as per WHO guidelines.
Write a note on historical overview of RA.

SHORT ESSAYS

7 x 5 = 35 Marks

3. Explain the protocol for pilot-plant scale up for tablet production.
OR
4. Discuss the significance of quality risk management studies in technology transfer.
Name the various TT agencies in India. Explain TIFAC.
OR
5. Write the various applications of biostatistics in pharmaceutical product development.
What are the contents in the investigator's brochure?
6. Define TQM. What are the key elements of TQM?
7. Write brief note on QbD concepts? Give its advantages.
8. Explain the different modules of CTD.
9. What are the general requirement for submission of application for issue of COPP?

SHORT ANSWERS

10 x 2 = 20 Marks

10. write two importance of platform technology.
11. What is the purpose of SUPAC guidelines?
12. What is standard operating procedure?
13. Define process validation.
14. What is New drug application?
15. Write the functions of regulatory authorities
16. What are the benefits ISO 9000?
17. Differentiate between assignable and non assignable causes as per OOS.
18. What is CDSCO and COPP?
19. Two functions of state licensing authority.
