

Rajiv Gandhi University of Health Sciences, Karnataka

VII Semester B. Pharm Degree Examination – 17-Mar-2021

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. What are the different platform technology and explain.
OR
Discuss the granularity of TT process for API and excipients
2. Discuss in detail investigator's brochure.

7 x 5 = 35 Marks

SHORT ESSAYS

3. What are the objectives and significance of pilot-plant?
OR
Discuss about documentation and premises for TT as per WHO guidelines.
4. How bioequivalence are documented?
OR
Name the various regulatory authorities and write their responsibilities.
5. List out the goals of TT.
6. Explain the different phases of out of specification analysis (OOS).
7. Explain the significance of change control in quality management system.
8. Write a note on state licensing authority.
9. What are the responsibilities of CDSCO?

10 x 2 = 20 Marks

SHORT ANSWERS

10. Name any four general requirements for pilot-plant construction.
11. What are the different parts in batch manufacturing record?
12. What is drug master file?
13. Define technology transfer according to WHO.
14. What is Dossier?
15. What are the types of IND?
16. Define confidentiality agreement.
17. What is six sigma?
18. What are the benefits of QbD?
19. Name the different modules of CTD.
