

Rajiv Gandhi University of Health Sciences, Karnataka

IV Year B.Pharm Degree Examination – NOV 2016

Time: Three Hours**Max. Marks: 80 Marks**

TOTAL QUALITY MANAGEMENT (Revised Scheme - 2)

Q.P. CODE: 1974

Your answers should be specific to the questions asked
Draw neat labeled diagrams wherever necessary

LONG ESSAYS (Answer any Two)**2 x 10 = 20 Marks**

1. Discuss the GMP requirement of Parenteral Department in detail.
2. Define auditing and explain in detail about management of auditing.
3. Explain the structure of ISO 9000 quality system standards.

SHORT ESSAYS (Answer any Eight)**8 x 5 = 40 Marks**

4. Explain TQM in brief.
5. Explain the procedures for registration.
6. Explain the objectives of WHO.
7. What are the requirements of documentation according to GMP?
8. Describe TGA guidelines and explain.
9. Explain market and manufacturing authorization.
10. Write a note on GMP procedures for returned and salvaged products.
11. Give the ICH guidelines for photo stability testing of new drug substances and products.
12. Write a note on drug substance solid-state characterization and stability.
13. What is Quality system manual? What are its contents?

SHORT ANSWERS**10 x 2 = 20 Marks**

14. What are the objectives of ISO?
15. What do you mean by work instructions?
16. Write a note on product quality?
17. Write a note on SOP?
18. What are the objectives of accelerated stability testing?
19. What features does ISO 9001 cover?
20. Give the relevance of Documentation.
21. Name Physical Testing methods to probe drug substance.
22. What is process validation?
23. What is the importance of pre-registration stage?