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Rajiv Gandhi University of Health Sciences, Karnataka

IV Year B.Pharm Degree Examination – Aug / Sep 2011

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 ICH recommendations of stability testing of solid dosage forms
2. What is auditing? Explain advantages and different types of auditing
3. List out and briefly explain the elements of US FDA guidelines

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

4. Explain the advantages of ISO 9000 series
5. What is quality system manual? What are its contents?
6. Explain the significance of master production records
7. Describe minimum labeling requirements for finished products
8. Write a note on quality manual
9. Write a note on limitations of accelerated stability testing
10. Mention the elements of ISO 9000 system
11. Differentiate between quality control and quality assurance
12. Write a note on salient features of MCA guidelines
13. Explain how cross contamination can be prevented during production

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

14. What do you mean by product recall?
15. What do you mean by good manufacturing practice?
16. Write a note on SOP
17. Define the terms accuracy and precision as per ICH
18. Why is it necessary to maintain good documentation practices?
19. Write a note on vender development
20. What does ISO 9001 stand for?
21. What are the features of International standards? What are the advantages of following them?
22. Who is responsible for quality of the finished product made by any manufacturing industry?
23. What is the importance of ISO certification in export of pharmaceuticals?

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