

Rajiv Gandhi University of Health Sciences, Karnataka

IV Year B.Pharm Degree Examination – Sep 2012

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. What is ISO? What does ISO 9000 series stand for? What are their quality elements?
2. Describe GMP requirements of production area as per schedule M
3. What is validation? Explain process validation and the different steps involved in it.

SHORT ESSAYS (Answer any Eight)

8 x 5 = 40 Marks

4. What factors influence 'Total Quality'?
5. Describe kaizen philosophy
6. Explain types of Audit
7. Write the importance of Master production control record.
8. What are the components of a quality manual?
9. Mention the function of US-FDA?
10. Write a note on vendor selection.
11. Write a note on the seven tools of quality
12. Write a note on limitations of accelerated stability testing.
13. Explain the purpose and contents of procedural manual.

SHORT ANSWERS

10 x 2 = 20 Marks

14. Define QC and QA
15. What is the objective of writing a good SOP.
16. When are products recalled from the market?
17. What is benchmarking process?
18. What is Quarantine?
19. List any two quality statements?
20. Define calibration.
21. Expand TGA and ICH
22. Write application of control charts
23. Explain the importance of Pre-registration.
