

Rajiv Gandhi University of Health Sciences
First Year M. Pharm Degree Examination - Oct/Nov 2014

[Time: 3 Hours]

[Max. Marks: 100]

GOOD MANUFACTURING AND LABORATORY PRACTICE

(RS 2 & RS 3)

Q.P. CODE: 9204

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

LONG ESSAY (Answer any TWO)

2 X 20 = 40 Marks

1. Explain the process of recovered goods, remarking and reprocessing
2. Write a note on good warehousing practices
3. Explain the elements of ISO 9000 : 2000 in detail

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Explain the stability testing of drug product as per ICH guidelines
5. Explain the premises requirement for a non-sterile dosage from manufacturing unit as per schedule M
6. Write a note on inventory control
7. Explain the process of handling returned goods
8. Explain the analytical method validation as per ICH guidelines
9. Explain clean in place and sterile in place

SHORT NOTES

2 X 5 = 10 Marks

10. Differentiate the GLP requirements of formulation plant and bulk drug plant
11. What is quarantine? Explain its significance

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