

Rajiv Gandhi University of Health Sciences
First Year M. Pharm Degree Examination - Nov 2011

[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 implementation of Good manufacturing Practices in bulk manufacturing unit as per schedule M.
2. Explain air – handling unit of a sterile manufacturing area
3. Explain the Types, design and elements of good warehousing practices

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Classify ICH guidelines. Name at least four guidelines under each category
5. Write a note on personnel training
6. Explain the process of distribution and distribution control
7. Define and classify validation. Explain the validation of equipments
8. Explain the contents of a batch manufacturing record
9. Write a note on label control

SHORT NOTES

2 X 5 = 10 Marks

10. Differentiate Quality Assurance and Quality Control
11. Explain the importance of preventive maintenance

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