

Rajiv Gandhi University of Health Sciences
First Year M. Pharm Degree Examination - May 2013

[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. a) Describe in detail about the applications of Modern equipments in practical GLP
b) What are the differences between FDA guidelines and schedule 'M' proposed by govt. of India.
2. a) Write the specific requirements for the manufacturing area of sterile products
b) Discuss the concepts of production planning and control
3. a) Distinguish between quality control and quality assurance
b) Give a note on ISO 9000.

SHORT ESSAY (Answer any FIVE)**5 X 10 = 50 Marks**

4. Discuss the product recall with reference to recall procedures
5. List out the various responsibilities of a qualified personnel in a manufacturing unit.
6. Explain briefly about utilities and facilities of organization
7. What are the precautions to taken to maintain sanitation?
8. Define the term process validation and explain the terms prospective and retrospective validation
9. Give a note on ICH guidelines followed by industries while the preparation of sterile products

SHORT NOTES**2 X 5 = 10 Marks**

10. Give an account of evaluation of complaints
11. Write a note on master formula records

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