



[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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