



[Time: 3 Hours]

[Max. Marks: 100]

QUALITY ASSURANCE

PAPER III

(RS 2 & RS 3)

Q.P. CODE: 9293

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 content, format and control of master formula record, batch manufacturing record and batch packing record
2. Name and explain different types of sterilization along with their merits and demerits
3. Explain GLP in detail

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. What is total quality management? Explain
5. What is clean in place? Explain the methods of attaining and ensuring the same
6. Write a note on vendor validation
7. Name different types of primary packing materials used for pharmaceuticals. Explain the sampling and quality control of labels
8. Write a note on good warehousing practices
9. What is a recall? What are the types of recall and how are they handled

SHORT NOTES

2 X 5 = 10 Marks

10. What is the importance of personnel training in implementing GMP
11. Write objectives and benefits of ISO 9000:2000

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