



[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 20 quality parameters of ISO 9000.
2. Write a note on location, design and layout of a non – sterile pharmaceutical manufacturing unit as per schedule M
3. Explain in process quality control (IPQC) tests for solid oral dosage form under the following
 - a) Significance
 - b) Sampling method
 - c) Sample analysis

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Explain label control
5. Classify audit. Explain internal audit
6. Write the importance of good warehousing practices
7. Discuss the implications of environmental protection act on quality of pharmaceuticals
8. What are returned goods? Explain the reasons for return of the goods and handling of the same
9. Explain the salient features of GLP systems

SHORT NOTES

2 X 5 = 10 Marks

10. What is a patent? Discuss the merits and demerits of patenting
11. How "Hatch – Waxman Act" has affected Indian pharmaceutical sector

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