



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.

LONG ESSAY (Answer any TWO)

2 X 20 = 40 Marks

1. Discuss in detail the various aspects of quality control laboratory responsibilities and briefly deal on controls on animal house.
2. Elucidate in detail the concepts of TQM, philosophy of GLP and ISO 9000.
3. What is SOPs? Write SOPs for any operating pharmaceutical machinery used in manufacturing of sterile dosage form. Add a note on Quality audits of manufacturing facilities.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Discuss the Drugs and Cosmetics Act and other relevant rules.
5. Write the importance and various aspects of Environmental Protection Act and Consumer Protection Act.
6. Write the practice for selection, purchase and maintenance of raw materials and add a note on selection of vendors.
7. Discuss the various aspects of In-process quality controls for non-sterile solid dosage form.
8. Describe the procedures for waste and scrap disposal. Comment on the records to be maintained.
9. Write the methodology employed for finished product release.

SHORT NOTES

2 X 5 = 10 Marks

10. Loan license and contract manufacture
11. Regulatory drug analysis

* * * * *