



**Quality Assurance
(Revised Scheme 4)**

Q.P. CODE: 9361

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. Explain in detail quality audits of manufacturing processes and facilities. Write a note on audits of quality control.
2. Write a typical standard operating procedure for a 16-station rotary tablet compression machine.
3. Write a note on "Investigator Brochure" as per ICH E6 guidelines.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Write a note on qualification and training of a new quality control chemist and new production chemist as per schedule M.
5. A batch of enteric-coated tablets failed to meet disintegration specifications. Explain the investigation process and CAPA (Corrective and Preventive Actions) for the same.
6. Name and explain the significance of any three "In Process Quality Control Tests" for injections and capsules.
7. Write a standard testing protocol for the assay of Paracetamol tablets IP.
8. Write a note on "Good Warehousing Practices".
9. Write a note on new drug product registration in United States of America.

SHORT NOTES

2 X 5 = 10 Marks

10. What are Trademarks and Copyrights?
11. What are online, inline and atline testing as per PAT guidelines of USFDA?

* * * * *