[Time: 3 Hours] [Max. Marks: 100]

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

- Classify recalls as per UFDA guidelines and explain each class in detail.
- Explain the importance of Q1, Q2 and Q9 guidelines of ICH.
- Write a note on essential documents to be maintained for the conduct of clinical trials as per ICH E6 guidelines.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

- Explain the control and reconciliation of packaging materials.
- 5. List the batch release documents. Briefly explain the process of batch release.
- Write a note on principles of scrap management.
- 7. What is annual product quality review and how is it done?
- A batch of tablets failed to meet dissolution specifications. Explain the investigation process and CAPA (Corrective and Preventive Actions) for the same.
- What is the importance of IPR (Intellectual Property Rights) in pharmaceutical sector? Explain the steps involved in filing IPR.

SHORT NOTES 2 X 5 = 10 Marks

- 10. List the modules of ANDA (Abbreviated New Drug Application) and write one sentence on each.
- 11. What is the focus of ISO 14000 and why is it important for pharmaceutical sector?

