Rajiv Gandhi University of Health Sciences

First Year M. Pharm Degree Examination - NOVEMBER 2015

[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**

1. Classify recalls as per UFDA guidelines and explain each class in detail.
2. Explain the importance of Q1, Q2 and Q9 guidelines of ICH.
3. 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**

4. Explain the control and reconciliation of packaging materials.
5. List the batch release documents. Briefly explain the process of batch release.
6. Write a note on principles of scrap management.
7. What is annual product quality review and how is it done?
8. A batch of tablets failed to meet dissolution specifications. Explain the investigation process and CAPA (Corrective and Preventive Actions) for the same.
9. 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?

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