Rajiv Gandhi University of Health Sciences

First Year M. Pharm Degree Examination - May 2016

[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. Discuss the Responsibilities, Training and Hygiene requirements for person working in sterile and non-sterile manufacturing areas.
2. Write a note on ICH guidelines with special emphasis on Q-series.
3. Discuss GLP protocols on Non-clinical testing and Control on animal house.

SHORT ESSAY (Answer any FIVE) **5 X 10 = 50 Marks**

4. Discuss the importance of Post Marketing Surveillance, Pharmacovigilance, BABE (Bioavailability and Bioequivalence) studies in clinical studies.
5. Describe In-Process Quality Control (IPQC) tests for Enteric coated tablets and specify the Pharmacopoeial recommended limits.
6. Write a note on European guidelines for contract manufacturing.
7. Write Master Formula for Sodium Chloride 0.9% injection.
8. Discuss the concepts of ISO 9001:2008.
9. Describe the quality information required for Product Registration by CDSCO (Central Drugs Standard Control Organization).

SHORT NOTES **2 X 5 = 10 Marks**

10. Waste and Scrap disposal procedure in tablet manufacturing
11. Corrective Action and Preventive Action (CAPA)

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