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Rajiv Gandhi University of Health Sciences

First Year M. Pharm Degree Examination – Nov 2011

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

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. Answer all questions

LONG ESSAY (Answer any TWO) **2 X 20 = 40 Marks**

1. Explain the location, plan and layout requirement for a sterile dosage form manufacturing unit
2. Write a note on planning, execution and closing of regulatory audit of a pharmaceutical manufacturing unit
3. Differentiate loan license manufacturing and contract manufacturing. Explain the implementation of GMP for these activities

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

4. Write a note on personnel hygiene
5. Explain the methods and precautions for control of contamination in non sterile dosage forms
6. Write a typical purchase specifications and maintenance SOP for HPLC with UV detector
7. Explain the salient features of factory Act
8. What are batch release documents? Explain each document in detail
9. Write a note on cleaning validation

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

10. Explain reprocessing of non – sterile dosage forms with special emphasis on stability
11. Write a note on retention sample

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