

**Rajiv Gandhi University of Health Sciences**  
**First Year M. Pharm Degree Examination – May 2013**

[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. Give a brief account on complaints and recall procedures of pharmaceutical products
2. Discuss about the development of standard operating procedure for the compression and coating of tablets
3. Describe in detail about the procedure for the disposal of waste for pharmaceutical industry and outline the methods of record maintenances for this purpose

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

4. Write briefly on:
  - a) ISO 9000
  - b) USFDA guidelines for the establishment of non clinical testing laboratories
5. Explain in detail about the procedures involved in the GMP certification
6. Write short notes on
  - a) Line Clearance
  - b) Master formula
7. Discuss the following:
  - a) Material management
  - b) GLP protocols on clinical testing
8. What are the materials to be sampled in pharmaceutical industry? Discuss in detail
9. What is patent? What are procedures to be followed to obtain a patent?

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

10. Briefly enumerate the evaluation of complaints
11. Write notes on handling of return goods

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