

Rajiv Gandhi University of Health Sciences
First Year M. Pharm Degree Examination – Oct/Nov 2014

[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. What is Industrial hygiene? How do you organize your formulation unit with special reference to location, maintenance and sanitation.
2. Explain the good warehousing practices with special emphasis on:
(a) Design of material of construction.
(b) Store management.
3. (a) Explain the techniques adopted in air control and particulate control.
(b) Write in detail about the UFDA guidelines on GMP.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Discuss the following in detail:
(a) Globalization of drug industries.
(b) Evaluation of complaints.
5. Write the objectives of the following:
(a) Quality audit.
(b) Industrial hygiene.
6. Write notes on:
(a) Recent amendments in Drugs and Cosmetics Act.
(b) Quality review.
7. Write the ISO structure and composition of policy development committees in detail.
8. Describe about the In Process Quality Control with respect to non-sterile products.
9. What is patent? What are the procedures to obtain a patent?

SHORT NOTES

2 X 5 = 10 Marks

10. Briefly enumerate the selection of vendors.
11. Write notes on scrap disposal procedure.

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