Rajiv Gandhi University of Health Sciences

Second Semester M. Pharm Degree Examination – JAN-2019

[Time: 3 Hours] [Max. Marks: 75]

Audits and Regulatory Compliance -II

Q.P. CODE: 5163

Your answers should be specific to the questions asked.
Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. What is cGMP? Explain cGMP Regulations and management responsibilities during audit in pharmaceutical manufacturing environment.
2. Give the questionnaire list in the auditing of ware house and weighing department.
3. Describe product and process information auditing in the microbiological laboratory.
4. Explain the auditing of engineering department in the pharmaceutical industry.

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. What are different types of auditing? Describe the planning process of the Auditing.
6. What is the importance of the auditing and discuss on the auditing reports.
7. Explain the auditing of the manufacturing operations in vendor production department.
8. Write about the GMP evaluation activities for audit in manufacturing environment.
9. Write a note on auditing check list for capsule manufacturing department.
10. Give the audit check list for tablet coating in manufacturing department.
11. What are different types of waters? Write a brief note on auditing of water in the microbiology laboratory.
12. Write a note on auditing of 'raw material' control in the microbiology laboratory.
13. Explain HVAC audit.
14. Write a note on the audit check list of 'environment treatment plant'?

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