Rajiv Gandhi University of Health Sciences

Second Semester M. Pharm Degree Examination - MAY-2018

[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. Describe cGMP Regulations and Resources in pharmaceutical Manufacturing Environment.
2. Explain granulation procedures for pharmaceutical product and give the check list for auditing.
3. Describe product and process information auditing in the microbiological laboratory.
4. Give a detail account on the Q.A department maintenance for auditing.

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

5. What is the purpose of auditing? How auditing team is selected in the Q.A department?
6. Write about the internal audit, external audit and auditors.
7. What is GMP? Explain the functions of GMP during training to quality system.
8. What are salient features in auditing a Vendor? Why it is essential.
9. Discuss about the packaging of the dry production and give its check list for audit.
10. Give details about auditing of coating materials used in a film coating of solid oral pharmaceutical product.
11. How are metrological audits performed in microbiological laboratory?
12. How do you classify and report deficiencies found during audit.
13. Describe the check list of water and water for injection while auditing of Quality Assurance.
14. Note on the audit of Efficient Treatment Plant (ETP).

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