Rajiv Gandhi University of Health Sciences

Second Semester M. Pharm Degree Examination - JUNE 2019

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

Audits and Regulatory Compliance

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 are the roles of organizational and personnel as per Schedule M of the Drug and Cosmetic Act, how are they audited?
2. Explain in detail on how you audit the supplier of a critical excipient.
3. Give a comprehensive audit checklist of pharmaceutical production systems and their rationale.
4. Give the comprehensive objectives of pharmaceutical audits and their necessity in ensuring the quality.

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

5. Write a note of auditing of building and facilities of a pharmaceutical production unit.
6. Briefly explain the responsibilities of auditors of auditees during a regulatory audit.
7. Explain the auditing procedure of auditing water systems in a pharmaceutical production facility.
8. Explain how tableting procedures of a solid oral pharmaceutical product are audited against the BMR.
9. Explain the auditing of a blister packing line.
10. How are Good Warehousing practices audited?
11. Give a brief overview of auditing roles of the QAU.
12. Explain the audits of pharmaceutical water systems.
13. How are audit checklists prepared?
14. Give a brief overview of auditing pharmaceutical manufacturing operations.

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