Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - JAN-2019

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

Quality Management System

Q.P. CODE: 5102

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 GMP requirements as per schedule M. Explain its scope.
2. Discuss about six system inspection model of USFDA.
3. How root cause determination and analysis is done? Explain.
4. How will you assign and prioritize risk in pharmaceutical development as per ICH Q9.

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

5. How strategic planning and implementation contributes to quality in pharmaceutical industry.
6. Describe principles of six sigma.
7. Discuss about handling and evaluation of complaints in pharmaceutical industry.
8. Enlist and explain attribute control charts.
9. Describe process of batch review and batch release.
10. Explain the scope of 21 CFR Part 11.
11. Elaborate the application of McKinsey's 7S model.
12. How do you think risk review process contributes to improve quality?
13. Explain the scope and salient features of NABL accreditation.
14. What is OOS? Distinguish OOS from OOT.

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