Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination – JAN-2019

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

Good Regulatory Practices

Q.P. CODE: 5121

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. Write in detail about types of validation and validation master plan.
2. Write essay on US cGMP part 210 and part 211.
3. Write in detail about principles and requirement of GALP.
4. Enumerate in detail about GLP inspection process.

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

5. Write a note on out of specification.
6. Write briefly about GLP regulations.
7. Write a note on validation of water systems.
8. Write about documentation process in GDP.
9. Write briefly about concept of quality.
10. Write a note on six sigma concept.
11. Write briefly about cGMP guidelines with respect to medical devices.
12. What are audit tool of GLP.
13. Write a note on validation master plan.
14. Stability testing principles of GDP.

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