Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - MAY-2018

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

Pharmaceutical Validation

Q.P. CODE: 5113

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. Discuss the history and various phases of Drug development and Drug approvals such as IND, NDA and ANDA.
2. Elaborate on URS, FAT, SAT and Requalification of a manufacturing equipment.
3. Explain the significance of Qualification for analytical instruments? Describe the qualification of FTIR Spectrometer.
4. Write in detail the validation of utility systems in Pharmaceutical Industry with emphasis on HVAC system.

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

5. Define Validation and write about Validation Master Plan.
6. How is qualification of Disintegration apparatus done?
7. Explain the qualification of volumetric flask.
8. Write types of sampling methods in Cleaning Validation.
9. Write the qualification of Pharmaceutical water system utility.
10. How is accuracy and precision determined in Analytical Method Validation?
11. Discuss the regulatory aspects of Pharmaceutical drug manufacture.
12. Write the salient features of Consumer Protection Act.
13. Explain types of Validation in Pharmaceutical Industry.
14. Write a note on maintaining status for Calibration, preventive maintenance and change management of manufacturing equipments.

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