Rajiv Gandhi University of Health Sciences

First Year M. Pharm Degree Examination - MAY-2018

[Time: 3 Hours] [Max. Marks: 100]

Analytical Assurance
(Revised Scheme 4)
Q.P. CODE: 9363

Your answers should be specific to the questions asked.
Draw neat, labeled diagrams wherever necessary. Answer any ten questions.

LONG ESSAY (Answer any TEN) **10 X 10 = 100 Marks**

1. Explain in detail the WHO requirements for the standardization of Herbal substances, preparations and products.
2. Explain the concepts of a) Accuracy and b) Precision in an analytical method.
3. What are the factors to be considered during sample preparation for HPLC analysis of drug products? What is Phase appropriate method development?
4. What is Performance Verification? Explain the terms: Design Qualification, Installation Qualification and Operational Qualification?
5. Explain in detail sterility testing methodology of pharmaceutical products as per IP requirements.
6. Discuss the chemistry and concept and chemistry of Bacterial Endotoxin testing of sterile products.
7. Explain the concept of ELISA and its application as the diagnostic test for HIV.
8. Explain briefly on statistical approaches in Bioassay. How do you estimate of safe doses?
9. Explain in detail application of Near Infra-Red spectroscopy in pharmaceutical manufacturing.
10. Enumerate and elaborate different steps for Stability Indicating Assay Methods (SIAM).
11. Explain preservative efficacy or antimicrobial effectiveness testing as per USP.
12. How do you set limits for residual solvents in drug substance as per ICH Q3 guidelines?

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