Rajiv Gandhi University of Health Sciences

First Year M. Pharm Degree Examination - JAN-2019

[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 the validation of analytical method by LC as per ICH guidelines.
2. Discuss in detail the identification and characterization of impurities by AAS/ICPMS.
3. Explain the harmonized methods for microbiological limit test.
4. Discuss the sample preparation and validation parameters for bio-analytical method as per USFDA guidelines.
5. Explain the different steps involved in development and validation of SIAM.
6. Explain the WHO requirements for standardization of herbal substances and herbal products.
7. Discuss in detail different types of ELISA methods.
8. Explain Primary bioassay screening and high through put screening.
9. Explain in detail the concept and chemistry of bacterial endotoxin test for sterile products.
10. Discuss the similarities and differences in principles of SEM (Scanning Electron Microscopy) and TEM (Transmission Electron Microscopy).
11. Discuss the parameters for qualification of GC.
12. Explain preservative efficacy testing procedure as per USP.

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