



Rajiv Gandhi University of Health Sciences, Karnataka

First Year M. Pharm Degree Examination – Oct/Nov 2014

Time: Three Hours

Max. Marks: 100 Marks

CHEMICAL & BIOLOGICAL EVALUATION (Revised Scheme 4)

Q.P. CODE: 9360

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

LONG ESSAYS (Answer any Two)

2 x 20 = 40 Marks

1. a) Method of preparation of SOPs with an example.
b) WHO certification regulations for export of Pharmaceuticals. (10+10)
2. a) Discuss the concepts, methodology and interpretation of official methods of Pyrogen testing.
b) Describe the principle involved in zone of inhibition and zone of exhibition with appropriate example. (10+10)
3. a) Principle and procedure involved in biological assay of (i) streptokinase (ii) oxytocin.
b) State ICH Q3C guidelines. (12+8)

SHORT ESSAYS (Answer any FIVE)

5 x 10 = 50 Marks

4. Describe the methods for biological sample preparation.
5. Write briefly about the sterility testing methods.
6. Mention the chemical analysis of potable water.
7. Write short notes on
i) Development of drug information profiles.
ii) Quality audit.
8. Describe the process of Cleaning validation.
9. Describe the procedure involved in calibration of UV-Visible spectrophotometer.

SHORT NOTES

2 x 5 = 10 Marks

10. Application of computers in quality control laboratory.
11. Salvaging of returned goods.

