

# 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.

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