

# Rajiv Gandhi University of Health Sciences, Karnataka

## First Year M. Pharm Degree Examination – MAY 2016

**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. Explain in detail about GLP and WHO certification for export of pharmaceuticals.
2. a) Explain calibration of UV-Visible Spectrophotometer and HPLC.  
b) Discuss Solid phase micro extraction and biological method validation as per ICH guidelines. (10+10)
3. Explain microbiological validation with examples and sterility testing methods.  
b) Discuss the concept of enzyme immuno assays with example. (10+10)

**SHORT ESSAYS (Answer any FIVE)****5 x 10 = 50 Marks**

4. Discuss drug rules of Schedule M and reprocessing and salvaging of returned goods.
5. Write in detail principle and procedure involved in the biological assay of streptokinase and tuberculin purified protein derivative.
6. Discuss Q<sub>3</sub>B and Q<sub>3</sub>C ICH guideline.
7. Give source, chemistry and properties of endotoxins and explain official pyrogen testing methods.
8. Explain cleaning and personnel validation.
9. Write on development of drug information profile and microbial assays of antibiotics.

**SHORT NOTES****2 x 5 = 10 Marks**

10. Write a note on concepts of Laboratory Information Management System (LIMS).
11. Write a note on test of antimicrobial preservatives.

\*\*\*\*\*