



**CHEMICAL AND BIOLOGICAL EVALUATION**

**PAPER IV**

**(RS 2 & RS 3)**

**Q.P. CODE: 9224**

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

**LONG ESSAY (Answer any TWO)**

**2 X 20 = 40 Marks**

1. Explain 21 CFR- Application of computer in quality control laboratory.
2. Elaborate the SOPs for operating pharmaceutical machinery.
3. Discuss the planning, design and plant layout of a pharmaceutical industry.

**SHORT ESSAY (Answer any FIVE)**

**5 X 10 = 50 Marks**

4. Compare and contrast the pyrogen testing as per I.P., B.P. and U.S.P. methods.
5. What are the criteria to constitute salvaging of returned goods and reprocessing?
6. Explain the principles and procedure involved in the Biological assay of Rabbits and Plague vaccines.
7. How do you calibrate the analytical instrument? Write in brief about the sampling techniques.
8. Write notes on development of drug information profile.
9. Give an account of Sterility testing methodology and how do you interpret?

**SHORT NOTES**

**2 X 5 = 10 Marks**

10. Write notes on biological assay of Chorionic Gonadotrophin.
11. Write the properties of bacterial pyrogen and endotoxin.

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