

Rajiv Gandhi University of Health Sciences, Karnataka

First Year M. Pharm Degree Examination – NOV 2016

Time: Three Hours**Max. Marks: 100 Marks**

QUALITY ASSURANCE (Revised Scheme 4)

Q.P. CODE: 9361

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. Write Standard Operating Procedures (SOP) for cleaning, filling, drying and compression.
2. Write a note on location, design and lay-out of a non-sterile pharmaceutical unit as per schedule M.
3. What is QSEM? Write in detail with special emphasis on Q series guidelines.

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

4. Write in details the quality control of packaging materials used in pharmaceutical unit.
5. Write a note on distribution of records used in pharmaceutical industry.
6. A batch of tablets failed for dissolution specifications. Explain investigation process and CAPA.
7. Describe preventive maintenance protocol for equipments used in pharmaceutical industry.
8. Write about quality review of finished product.
9. Explain BA BE studies (bioavailability and bioequivalence).

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

10. Describe the basic concepts of IND and NDA.
11. Explain briefly preventive maintenance protocol for equipments.
