

Rajiv Gandhi University of Health Sciences, Karnataka

Sixth Semester B. Pharm Degree Examination – 14-Jun-2024

Time: Three Hours

Max. Marks: 75 Marks

PHARMACEUTICAL QUALITY ASSURANCE

Q.P. CODE: 5028

Your answers should be specific to the questions asked.

Draw neat labeled diagrams wherever necessary.

All the Questions are compulsory

LONG ESSAYS

2 x 10 = 20 Marks

1. Discuss in detail about the concepts of Quality Assurance and GMP.

OR

Explain about the quality control tests for containers and rubber closures.

2. Describe the design, construction and plant layout of a production unit.

SHORT ESSAYS

7 x 5 = 35 Marks

3. Discuss the tools and elements of QbD program.

OR

Explain the protocol for conduct of non- clinical laboratory study.

4. Write a note on NABL Accreditation.

OR

Describe briefly regarding equipment selection and purchase specification for raw materials.

5. Write briefly about Master Formula Record.

6. Describe the maintenance of sterile area facilities.

7. Write a note on Good ware house practices.

8. What is DMF and explain its contents.

9. Summarize the reasons for disqualification of testing facility.

SHORT ANSWERS

10 x 2 = 20 Marks

10. What is the difference between Quality Assurance and Quality control?

11. Define standard operation procedure (SOP).

12. What is BMR?

13. Define calibration and validation.

14. Mention the elements of ISO 9000.

15. What is Quality Audit

16. What is contamination and cross contamination?

17. Define Validation Master Plan.

18. What are secondary packing materials give example.

19. Define accuracy and precision.
