

QP CODE: 213329

Reg. No:.....

**Second Semester M. Pharm Degree Supplementary Examinations
August 2021**

M.Pharm (Pharmaceutical Analysis)

Paper III: Quality Control & Quality Assurance (MPA 203T)

Time: 3 Hours

Total Marks: 75

- *Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space*
- *Answer all parts of a single question together • Leave sufficient space between answers*
- *Draw table/diagrams/flow charts wherever necessary*

Essays

(3x10=30)

1. Enlist the various IPQC and Finished Products Quality Control Tests carried out for parenterals and ophthalmic preparations. Explain in detail the sterility testing of parenteral products.
2. Explain in detail the environmental control and utilities in a sterile manufacturing unit.
3. Discuss in detail the preparation of protocol for the conduct of non-clinical laboratory testing as per GLP.

Short Notes

(9x5=45)

4. Explain master formula record.
5. Discuss in brief the training protocol for the personnel employed in pharmaceutical manufacturing unit.
6. IPQC and Finished Products Quality Control tests carried out for ointments and creams.
7. Explain on purchase specifications for raw materials.
8. Discuss in brief quality audit plan and reports.
9. Explain three tier documentation in pharmaceutical industry. Explain.
10. Explain on mix ups and cross contamination.
11. Explain in brief expiry date calculation.
12. Discuss in detail aseptic process control.
