

QP CODE: 213329

Reg. No:.....

**Second Semester M. Pharm Degree Regular/Supplementary Examinations
November 2025**

M.Pharm (Pharmaceutical Analysis)

**Paper III: Quality Control & Quality Assurance (MPA 203T)
(Common for 2019 and 2024 Scheme)**

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 primary packaging materials used in parenteral preparations.
2. Explain in detail the drug industry location, design, construction, and plant lay out for a sterile manufacturing unit.
3. Discuss in detail the components of master formula record.

Short Notes

(9x5=45)

4. Compare and contrast the terms quality control and quality assurance.
5. Explain on control and maintenance of animal house as per CPCSEA guidelines.
6. Good warehousing practice.
7. Discuss in brief change in of components and change control.
8. IPQC and Finished Products Quality Control tests carried out for capsules as per IP.
9. Explain distribution records.
10. Discuss in brief three tier documentation in a pharmaceutical industry.
11. Explain the release of finished goods and process deviation.
12. Discuss in brief the various components of an SOP prepared in a pharmaceutical industry.
