

QP CODE: 213329

Reg. No:.....

**Second Semester M. Pharm Degree Regular/Supplementary Examinations
February 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. Explain in detail the location, design, construction and plant layout for a sterile manufacturing unit.
2. Discuss in detail the protocol for the conduct of non-clinical laboratory testing.
3. Enlist the various IPQC and FPQC tests carried out for tablet formulations. Explain in detail any three tests

Short Notes

(9x5=45)

4. Define the term quality control and quality assurance. Explain the concept in brief.
5. The distribution records.
6. Explain in detail the quality control tests carried out for ophthalmic ointments.
7. Describe the three tier documentation in pharmaceutical industry.
8. Batch formula record.
9. Explain in brief change control.
10. Expiry date calculation
11. The purchase specifications for raw materials in a pharmaceutical industry.
12. How do you monitor mix ups and cross contaminations in a pharmaceutical industry
