

QP CODE: 213329

Reg. No:.....

**Second Semester M. Pharm Degree Supplementary Examinations
September 2022**

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. Discuss in detail about the cGMP guidelines in accordance with USFDA and WHO guidelines.
2. Explain the quality control test for ointments and creams.
3. Define quality control and quality assurance. Distinguish between QC and QA. Describe in detail about the role of QA personnel in pharmaceutical industry.

Short Notes

(9x5=45)

4. Role and composition of animal ethical committee.
5. Sanitation procedure in pharmaceutical industry.
6. Batch formula record.
7. SOP (standard operating procedures)
8. Expiry date calculation
9. Electronic data.
10. Enlist the type of audits and explain internal audit.
11. Quality control test for closures.
12. Quality control test for capsules
