**QP CODE: 213329** **Reg. No:……**

## Second Semester M. Pharm Degree Regular/Supplementary Examinations October 2023

## M.Pharm (Pharmaceutical Analysis)

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

# (Common for 2017 and 2019 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. How an analytical method is validated as per ICH guidelines.
2. Explain the three types of documents in pharmaceutical industry. How each of them are controlled. Explain.
3. Explain the difference between aseptic process and sterile production. Explain using manufacturing of water for injection 5ml ampoule as a representative example.

**Short Notes** **(9x5=45)**

4. Explain the protocol for the conduct of non clinical testing.
5. Explain Quality control of finished products according to Indian Pharmacopoeia, for suppositories.
6. A company is manufacturing 100 liters batch of ibuprofen suspension in a batch. Write a process control plan for the same.
7. List the in process quality control test for an ointment with justification for each test.
8. Explain pharmaceutical inspection convention. What is its role in making affordable drugs available to the needy population.
9. Explain the release acceptance criteria and shelf life acceptance criteria. Can values of this be different for a same product justify.
10. Explain Master Formula Record.
11. List the sub titles of a standard operating procedure describing the operation of a UV – Visible spectrophotometer.
12. Explain the process deviation and how is it handled.

**********