QP CODE: 213329 **Reg. No:……**

Second Semester M. Pharm Degree Regular/Supplementary Examinations May 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. Explain good laboratory practices. Explain its major principles.
2. Explain lay out and construction of a non-sterile dosage form manufacturing unit as per 21 CFR 211.
3. How are the acceptance criteria for a specified impurity in a new drug substance and new drug product established. Explain in detail.

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

4. Explain the process of forming and implementing a new ICH guideline.
5. A drug product manufacturing company received 25 containers of 50 kg each paracetamol I.P. Write a sampling plan for the same
6. List the process quality control tests for immediate release tablets with justification for each test.
7. Explain the representative batch manufacturing record for the granulation operation of an immediate release tablet.
8. Classify audits. Explain the significance of each.
9. Compare and contrast the conventional paper based documents and electronic documents.
10. Who review production record. Why and how.
11. Explain the difference between mix up and cross contamination. How can they be prevented.
12. Ä drug product manufacturing company produces paracetamol syrup IP using ponceau 4R as colouring agent.Write a representative batch manufacturing record as per GMP guidelines

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