QΡ	CODE: 112329	Reg. No:

## First Semester M.Pharm Degree Supplementary Examinations February 2022 M.Pharm (Pharmaceutical Analysis)

Paper II: Advanced Pharmaceutical Analysis (MPA 102T)

(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. Describe the general principles and classification of residual solvent in impurity. Add note on its analytical procedures.
- 2. Explain the separation of bound and unbound drug in IA. Enzyme IA and applications of IA.
- 3. Discuss about WHO and ICH guidelines for stability testing in impurity profiling and degradent characterization

Short Notes (9x5=45)

- 4. Describe HPLC finger printing in stability testing of phytopharmaceuticals.
- 5. Biological assay of adsorbed diphtheria vaccine.
- 6. What are the stability testing protocol for storage condition.
- 7. Give the concepts of validation of accelerated stability testing.
- 8. The principle and procedures for instrument of PCR.
- 9. Define and classify impurity in drug substance as per ICH guidelines.
- 10. Discuss the reporting and control of degradation products of impurity in new drug product.
- 11. Analysis of carbon and sulphur in elemental impurity.
- 12. Radioimmunoassay.

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