First Semester M.Pharm Degree Regular/Supplementary Examinations April 2023 M.Pharm (Pharmaceutical Analysis)

Paper II: Advanced Pharmaceutical Analysis (MPA 102T)

## (Common for 2017 and 2019 Scheme)

### Time: 3 Hours

- 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

- 1. Discuss in detail about the stability studies and concepts of validation of accelerated stability testing and shelf life prediction.
- 2. Discuss the bioassay of oxytocin (any two methods) in detail
- 3. Define impurity. Classify the impurities present in the drug/ formulations. Discuss in detail about impurity profile of drugs as per International Council for Hormonisation guidelines

### Short Notes

- 4. Principle and procedure involved in the bioassay of the human anti-hemophilic vaccine B
- 5. Bioassay of heparin sodium IP
- 6. General analytical procedures for quantification of elemental impurities.
- 7. Regulatory requirements for Phytopharmaceuticals
- 8. Bioassay of tetanus toxoid
- 9. Short term stability studies of formulations.
- 10. Radioimmunoassay.
- 11. General analytical procedures for quantification of residual solvent.
- 12. Quantification and applications of immunoassay

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## QP CODE: 112329

## (3x10=30)

#### (9x5=45)

# Total Marks: 75

Reg. No:....