

### **AIM:**

According to the guidelines by ICH and FDA, stability testing is required to be performed to understand how environmental factors affect on the quality of drug substance and drug products. From the information on stability of molecule, information can be obtained on proper storage condition, shelf life and helps in proper selection of formulation and packaging condition. Considering this, the aim of the present work was to develop stability indicating assay methods and study of degradation behaviour for some selected drugs. Literature suggested that not much data is reported for Clevidipine butyrate, Acotiamide HCl Trihydrate, Fimasartan Potassium, Anagliptin, Efonidipine HCl Ethanolate and Riociguat. So it was thought of interest to develop simple and specific stability indicating assay method and study the degradation behaviour for these selected drugs.

### **OBJECTIVE:**

The specific objectives of the study were:

1. Clevidipine Butryate
  - a. Development and Validation of Stability Indicating Assay Method by HPLC
  - b. Development and Validation of Stability Indicating Assay Method by HPTLC
  - c. Statistical comparison of HPLC and HPTLC methods for Clevidipine
2. Acotiamide HCl Trihydrate
  - a. Development and Validation of Stability Indicating Assay Method by HPLC
  - b. Characterisation of degradation products by LC-MS
  - c. Isolation of major degradation products and characterisation by spectral techniques like IR, NMR and LC-MS
  - d. Prediction of possible degradation pathway
3. Fimasartan
  - a. Development and Validation of Stability Indicating Assay Method by HPLC
  - b. Characterisation of degradation products by LC-MS

- c. Isolation of major degradation product and characterisation by spectral techniques like IR, NMR and LC-MS
  - d. Study of degradation kinetics
  - e. Prediction of possible degradation pathway
4. Anagliptin
- a. Development and Validation of Stability Indicating Assay Method by HPLC
  - b. Characterisation of degradation products by LC-MS/MS
  - c. Isolation of major degradation product and characterisation by spectral techniques like IR, NMR and LC-MS
  - d. Study of degradation kinetics
  - e. Prediction of possible degradation pathway
5. Efonidipine HCl Ethanolate
- a. Method development by HPLC using QbD approach
  - b. Development and Validation of Stability Indicating Assay Method by HPLC
  - c. Characterisation of degradation products by LC-MS/MS
  - d. Isolation of major degradation product and characterisation by spectral techniques like IR, NMR and LC-MS
  - e. Study of degradation kinetics
  - f. Prediction of possible degradation pathway
6. Riociguat
- a. Development and Validation of Stability Indicating Assay Method by HPLC
  - b. Characterisation of degradation products by LC-MS/MS
  - c. Isolation of major degradation product and characterisation by spectral techniques like IR, NMR and LC-MS
  - d. Study of degradation kinetics
  - e. Prediction of possible degradation pathway