CHAPTER 3

AIM OF PRESENT WORK
Day by day numbers of newer drugs acting on CNS and their formulations either in single or in combined dosage forms are marketed as well as are under investigation.

During the formulation development and approval process for the marketing of new drug formulations, the regulatory authority, FDA demands stability data for a suitable time period suggested as per ICH guidelines.

Reported analytical methods for some drugs in literatures are limited for their estimation.

So there is always a need to develop and validate simple and cost effective analytical methods for the estimation of some newer drugs acting on CNS in bulk and their Pharmaceutical dosage forms.

Based on literature review, it was found that numbers of studies involving method development for estimation of Rufinamide and Lacosamide individually or in combination have been carried out in formulations but till date there is no stability indicating assay method reported for estimation of Rufinamide and Lacosamide by HPTLC as well as their degradation product characterization has not also been reported.

So, it was felt that there is a need to develop stability indicating method for estimation of Rufinamide and Lacosamide by HPTLC in bulk and their dosage form.

So present work is specific aimed to -

- Development of a validated stability-indicating HPTLC method for Rufinamide in bulk and its Pharmaceutical dosage form
- Isolation and characterization of degradation product of the drug after forced degradation
- Degradation kinetic study of Rufinamide
CHAPTER 3

AIM OF PRESENT WORK

- Development of validated, cost effective, more accurate stability indicating HPLC method for Rufinamide
- Development of validated Spectrophotometric method of Rufinamide
- Statistical comparative study between HPTLC, HPLC, and Spectrophotometric method for estimation of Rufinamide in bulk and Pharmaceutical dosage form
- Development of a validated stability–indicating HPTLC method for Lacosamide in bulk and its Pharmaceutical dosage form
- Isolation and characterization of degradation product of the drug after forced degradation
- Development of validated, cost effective, more accurate stability indicating HPLC method for Lacosamide
- Development of validated Spectrophotometric method of Lacosamide
- Statistical comparative study between HPTLC, HPLC, and Spectrophotometric method for estimation of Lacosamide in bulk and Pharmaceutical dosage form