Objectives of the study
The objective of this study was to develop and optimize chronomodulated drug delivery systems of montelukast sodium (MKS), a selective leukotriene receptor antagonist for chronic management of asthma and allergic rhinitis. The developed dosage forms were expected to release MKS after a lag time of 4 to 5 h.

The objectives were subdivided into the following specific aims:

- To develop and validate analytical and bioanalytical method for montelukast sodium as per ICH and USFDA guidelines
- To develop and optimize chronomodulated drug delivery systems of montelukast sodium
  - Time-controlled pulsatile release tablets
  - Osmotically controlled pulsatile release capsules
  - Delayed release beads
- Physicochemical characterization and in vitro release study of the developed formulations
- Stability studies of the optimized formulations
- To study pharmacokinetic behavior in rabbits