2. Research Objective

The primary objective of this research work was to prepare drug loaded pellets of ketorolac tromethamine and aceclofenac individually using solution layering technology and to give functional coating using various film forming polymers like hydroxy propyl cellulose and hydroxyl propyl methyl cellulose (HPMC) and release retarding polymers like ethyl cellulose (EC) to sustain the drug release.

Sustained release oral dosage forms of ketorolac tromethamine were not available in the market. In order to reduce the dosing frequency from three to four times a day to twice a day and improve patient compliance, an attempt was made to prepare sustained release formulation of ketorolac tromethamine and multi-particulate drug delivery system containing aceclofenac. Like other NSAIDs, ketorolac also causes gastric irritation. Local irritation derived from high local concentrations of a drug from a single-unit dose, can be avoided by pellet formulations. The dose of ketorolac is 10 mg. Since the dose of ketorolac is low, it can be efficiently layered over the non-pareil seeds by solution or suspension layering employing a pan coater. Ketorolac belongs to BCS class I, which is highly soluble and highly permeable. Therefore a hydrophobic polymer, ethyl cellulose is chosen as a secondary coating polymer so that it can retard the rate of drug release from the core.

The rationale of this study is to formulate and characterize an oral, multi-particulate drug delivery system containing aceclofenac which is a sustained release preparation intended for once-daily administration. A multiple unit formulation consisting of coated aceclofenac pellets and pan coating technology was employed in this
research project. The objective of this study was to prepare and to characterize drug loaded aceclofenac pellets using solution layering technology and to give functional coating using ethyl cellulose in combination with hydroxy propyl methyl cellulose and to extend the drug release for more than 24 hours. Here, ethyl cellulose acts as a release retarding polymer and hydroxy propyl methyl cellulose acts as film forming agent.

The process variables like batch size, coating pan speed, pump speed, spray pressure and temperature of the bed should be optimized in order to get efficient drug loading and uniform functional coating and for the optimized formulation, pharmacological evaluations like analgesic activity was checked.

The pellets were characterized for drug content, particle size distribution, flow properties, surface morphology and dissolution profile. In vitro dissolution studies were carried out using USP dissolution apparatus type I. The kinetic study of the drug was performed and it was revealed that the release of drug from the optimized formulation was appeared to follow first order kinetics. The dissolution profile and in vitro release kinetics showed that the pellets were promising for sustained delivery of the drug and have significant analgesic activity.