Ketorolac Tromethamine is a non-steroidal anti-inflammatory agent used to treat the conditions of moderate to severe pain. Aceclofenac is a phenyl acetic acid derivative, a newer derivative of the diclofenac group of non-steroidal anti-inflammatory drug (NSAID) that exhibits analgesic and anti-inflammatory activities which is used for oral administration. Due to its short biological half-life and dosing frequency, it is an ideal candidate for sustained release formulation.

Multi-particulate drug delivery systems of ketorolac tromethamine and aceclofenac were developed employing pan coating technology as these multi-particulates are more advantageous over single-unit systems because of their small size and offers several advantages such as rapid absorption, reducing peak plasma fluctuation and ease of administration and termination of therapy. Each pellet acts as a separate drug delivery unit and is designed to deliver the drug continuously over the dosage interval.

The aim of this research work was to formulate and evaluate ketorolac tromethamine and aceclofenac pellets employing pan coating technology. Ethyl cellulose was used as the release retarding polymer in development of this sustained release formulation. The best formulation was selected based on the in vitro dissolution studies.

Drug-excipient interaction studies were carried out by FT-IR in order to indicate the compatibility of drug with the polymers. The results revealed that the drugs and
polymers were satisfactorily compatible, without any significant changes in the chemical nature of the drug.

Eight formulations of ketorolac tromethaminewere prepared by varying the ratio of ethyl cellulose, hydroxy propyl cellulose and dibutylphthalate. These formulations were evaluated for various parameters like particle size analysis, surface morphology, percentage yield and invitro drug release studies. Invitro dissolution studies of formulations F1, F2, F3 and F4 showed that there was complete release of drug or formulations within 2 hrs. but formulation F8 containing 10% ethyl cellulose as retarding polymer was found to be the best formulation which showed 100 % of drug release in 12 hours.

Release kinetic study of formulations F1, F2, F3, F4 and F5 showed that they follow first order release. The release pattern of F6, F7 and F8 was biphasic characterized by initial burst effect in the first one hour followed by slow release of drug sustaining the release of drug upto 12 hours. Both phases have followed zero-order release. The mechanism of drug release was found that, on contact with aqueous fluids in the gastrointestinal tract (GIT), water diffuses into the interior of the particle. Drug dissolution occurs and the drug solutions diffuse across the ethyl cellulose coat.

Ketorolac optimized pellet formulation (F8) was screened for analgesic activity in mice and the same sample exhibited statistically significant (p<0.0001) analgesic activity at 10th hour in comparison to the standard (pure ketorolac solution).