1.1. AIMS AND OBJECTIVES OF THE INVESTIGATION

Easiest and predominant route of drug delivery is oral since long time. Since it is the most studied route since last decade, numerous oral delivery systems have been developed to act as drug reservoirs from which the active substance can be released over a defined period of time at a predetermined and controlled rate. An ideal sustained and controlled release delivery system should release the content continuously in an amount sufficient to maintain constant plasma levels once the steady state is reached.

More often, drug absorption is unsatisfactory and highly variable among and between individuals, despite excellent in vitro release patterns. The reasons for this are essentially physiological and usually affected by the gastrointestinal (GI) transit of the form, especially its GRT, which appears to be one of the major causes of the overall transit time variability. Over the past three decades, the pursuit and exploration of devices designed to be retained in the upper part of the GI tract has advanced consistently in terms of technology and diversity, encompassing a variety of systems and devices such as floating systems, raft systems, expanding systems, bioadhesive systems and low-density systems. Stomach specific (gastric-retention) will provide advantages such as the delivery of drugs with narrow absorption windows in the small intestinal region. Also, longer residence time in the stomach could be advantageous for local action in the upper part of the small intestine, as in treatment of peptic ulcer disease. Furthermore, improved bioavailability is expected for drugs that are absorbed readily upon release in the GI tract. These drugs can be delivered ideally by slow release from the stomach.

Thus various objectives were-

- Selection of a suitable drug for making gastro retentive systems
- Selection of suitable dosage form(s) for gastroretention.
- Design development and evaluation of gastro retentive systems using Formulation by Design
  - Formulation, optimization and evaluation of floating bioadhesive tablets
  - Formulation, optimization and evaluation of floating beads
- Validation of optimized products
- Comparison of optimized products with marketed formulation
- Stability studies of optimized products

Above said aims and objectives of the present work were chased by using Central Composite Design (CCD), where as per the Design of Experiment the polymers composition (tablet) and polymer and oil composition (beads) were changed for
getting the product with appropriate properties. *In vivo* retention of the products was ascertained using X-ray imaging technique. Optimized products were also compared with marketed samples. The products were tested for stability by doing accelerated stability studies in zone II conditions (40 ± 2°C/ 75 ± 5 % RH), as per ICH Q1 guidelines.