AIM AND OBJECTIVE
AIM AND OBJECTIVE OF THE STUDY

The aim of the study is to formulate the best enteric coating polymer which can provide sufficient protection to the anti-ulcer class of drugs and display the intended delay release action. Pantoprazole is a proton pump inhibitor; it inhibits specifically and doses proportionally the gastric H+, K+-ATPase enzyme which is responsible for acid secretion in the parietal cells of the stomach. Since these drugs undergo degradation in acidic conditions of stomach and irritates the gastric lining, it could be a plausible strategy to direct the drug to the intestine circumventing its release in the stomach. The most feasible carrier system which could achieve this goal is delayed release oral tablets by coating the tablets with suitable enteric film formers. Hence the present investigation aimed at formulation and evaluation of a delayed release dosage form of proton pump inhibitor class of anti-ulcer drug, by optimizing an enteric coating using novel polymeric film formers.

The objectives of the study includes,

- To formulate a delayed release tablet or oral administration of pantoprazole and Rabeprazole that could present the release of drug in the acid environment and immediately disintegrates in the intestinal milieu.
- To select the best tablet technique and to optimize the formulation by observing the influence of different tablet ingredients upon the performance of the end formulation.
- Selection of suitable excipients and optimization of their quantities for core tablet formulation using Correlation and Regression Analysis
- Enteric coating of the core tablet using novel enteric coating compositions including organic, hydro alcoholic and aqueous based coating polymers.
- To formulate the appropriate delayed release tablet with acceptable release pattern by altering the thickness of the enteric film by varying the polymeric weight gain and to test their performance and stability.
- To study various Kinetics of Drug release and determine kinetic parameters.
- To compare the performance of optimized enteric coated formulation in vivo by observing the gastrointestinal transit behaviour using radiographic technique.
- To perform In vivo drug release studies using Rabbit as the animal model.
PLAN OF WORK

Formulation of acid labile PPI drug

Development of delayed release enteric formulation

Characterization of API

Optimization of formulation

Direct compression

Granulation Technique

Effect of diluents

Effect of disintegrants

Effect of diluents

Effect of disintegrants

Effect of binders

Evaluation of precompression and post compression characteristics

Selection of optimized core tablet formulation

Seal coating

Enteric coating

Organic coating composition

Hydro-alcoholic coating composition

Aqueous coating composition
Fig. 26: Schematic representation of plan of study of the formulation of Delayed release tablets of Proton Pump Inhibitors