2. AIMS AND OBJECTIVES

The aim of the present work is to develop a controlled release formulation based on polymeric nanoparticles for an antiulcer drug lansoprazole.

Lansoprazole is a drug commonly used in the management of peptic ulcer in various conditions such as

✓ acid-related disorders of the upper GIT
✓ Gastro Oesophageal Reflux Disease
✓ benign gastric ulcer & duodenal ulcer
✓ heartburn and epigastric pain related with acid-related dyspepsia
✓ treatment of NSAID-associated benign gastric ulcers, duodenal ulcers
✓ long term management Zollinger-Ellison syndrome.

This drug, on regular usage, is reported to cause adverse effects including abdominal pain, diarrhoea, dizziness, skin rashes, angioedema, thrombocytopenia, impotence etc.

This drug is primarily metabolized by liver. Hence it is a need to reduce the dose to the hepatic and renal failure patients. But reduced dose in conventional systems may not produce required pharmacological effect.

Further the gastro-intestinal tract is exposed to different pH environment, which the lansoprazole may be wasted. Hence targeting of the drug to peptic ulcer should also be considered in designing a suitable drug delivery system.
The following are the specific reasons which demand the development of oral controlled drug delivery system -nanoparticles for lansoprazole:

- Due to its short half-life of 1-1.5 hrs, frequency of administration is increased. A well designed oral controlled delivery can reduce the frequency of dosing.
- Due to its severe side effects, controlled delivery - nanoparticles of lansoprazole at optimal concentration may be required.
- Comparing to other routes, oral route is preferable with respect to safety, comfort and reliability. Hence controlled delivery of lansoprazole by oral route is ideal.
- Controlled release of lansoprazole from nanoparticles will reduce the frequency of dosing and dose size and may increase patient convenience.
- Development of controlled delivery of lansoprazole may lead to patenting issues.
- Wide market opportunities are available

The overall aim and objective of the present work is to:

- Improve the overall therapeutic efficacy of lansoprazole by controlled release using nanoparticles drug delivery
- Targeting the drug to peptic ulcer cells.
- Minimize the adverse effects
- Reduce the overall dose and dosing frequency of lansoprazole
- Achieve improved patient compliance
To achieve the above said objectives the plan is executed

✓ To formulate one type of oral controlled drug delivery system – Nanoparticles of lansoprazole

✓ To evaluate the formulated products of nanoparticles of lansoprazole

✓ To optimize process and formulation variables

✓ To perform anti-ulcer activity

✓ To perform stability studies of optimized formulation