Chapter 2

Objective of the Work

2.0 OBJECTIVE OF THE WORK

The treatment for eradication of *Helicobacter pylori (H. pylori)* is very complicated. Current recommended regimes require higher dosage of the therapeutic moieties and frequent administration. It leads to various side effects and patient non-compliance. Most important reason for failure of anti *H.pylori* therapy is inability of the delivery systems in maintaining effective antimicrobial concentration for longer duration in stomach. Increasing failures in current anti H. pylori therapy is driving research towards exploring alternative therapeutic moieties and novel drug delivery strategies.

Drawbacks of the current anti *H.pylori* can be overcome and effectiveness of therapy can be improved by developing a Gastroretentive Drug Delivery System that can reside in the stomach for longer duration and release drug for longer duration. Sustained and site specific delivery may definitely maintain bactericidal concentration of the antimicrobial agents for longer duration in stomach and effectively eradicate H. pylori infection.

Amoxicillin, levofloxacin and clarithromycin are widely explored antibiotics in anti H.Pylori therapy and are currently delivered through conventional drug delivery systems. But failure rates are high because conventional formulations can not maintain higher antimicrobial concentration for longer duration in stomach. Hence objective of the present investigation was to develop novel gastroretentive formulations in the form of minimatrices and softgel for sustained delivery of amoxicillin, levofloxacin and clarithromycin in stomach for effective treatment of H.pylori infection.

The prime objectives of the present investigation were:

- To develop suitable analytical method for estimation of amoxicillin, levofloxacin and clarithromycin.
- To carry out preliminary formulation trials for selection of suitable excipients and manufacturing technique.
- To carry out drug excipient compatibility study.
- To design the formulations by using suitable experimental design such as central composite, full factorial design etc

- To evaluate the developed formulations for buoyancy, drug content, swelling, drug release pattern.
- To find out significance of the formulation variables on various response variables by using statistical techniques.
- To select the optimum formulation by desirability function approach.
- To carry out in vivo study for determining gastric residence time of the optimum formulation by gamma scintigraphy.
- To carry out stability study of the optimum formulation as per ICH guidelines.