Chapter VI

CONCLUSION
6. Conclusion

Floating drug delivery systems extend significantly the period of time over which the drugs may be released. Thus they not only prolong dosing intervals, but also increase patient compliance beyond the level of existing controlled release dosage forms. While the control of drug release profiles has been a major aim of pharmaceutical research and development in the past two decades, the control of GI transit profiles could be the focus of the next two decades and might result in the availability of new products with new therapeutic possibilities and substantial benefits for patients.

The present work demonstrated a facile approach to develop sunflower oil entrapped chitosan coated floating mucoadhesive alginate beads to increase the efficacy of amoxicillin trihydrate for eradicating *H. pylori* infection. The oil-entrapped alginate beads as core accomplished by ionotropic gelation method and were further coated with chitosan barrier. Total eight different batches are prepared varying the amount of oil (ml), polymer (mg) (Sodium alginate & HPMC) and coating agent (chitosan). The various physicochemical properties of the beads, in-vitro release of the drug, in-vitro floating time and lag time, in-vitro *H. pylori* growth inhibition, in-vitro stability of the drug and in-vivo floating time were evaluated. FTIR was also done in preformulation study to determine any kind of interactions. Surface study of the beads was also done by SEM.

These developed floating beads exhibited good mucoadhesive property (mucoadhesiveness of $76.00 \pm 2.00\%$ to $84.67 \pm 3.215\%$), excellent drug entrapment efficiency (DEE of $55.19 \pm 4.259 \%$ to $90.90 \pm 2.508 \%$), appreciate in-vitro buoyant ability (floating duration $>24$ h) with a minimum buoyant lag time ($<46.33 \pm 3.215$ seconds), and ensure drug release beyond 7 h. Here, actually beads that were both modified with oil and coated provided the best combined buoyancy, mucoadhesion and release profile. SEM photographs revealed that the beads were spherical in shape with oil filled channels distributed throughout the surfaces. The
in-vitro \textit{H. pylori} inhibition study showed the good antimicrobial activity for formulated beads (AT8) in in-vitro \textit{H. pylori} growth culture. Furthermore, X-ray study in rabbit stomach confirmed the gastric retention of optimized formulation (AT8) proving its efficacy as stomach-specific delivery of the drug.

The method for the preparation of floating alginate beads followed was very simple and economic. No organic solvent was used. The polymers used are biodegradable and the vegetable oil (Sunflower oil) used is an edible oil. So, this method is acceptable from Safety, Health and Environment (SHE) point of view. Therefore, the modification of calcium alginate beads with sunflower oil with further coating with chitosan can ensure the development of good floating mucoadhesive drug delivery devices for intragastric delivery of bioactive molecule in \textit{H. pylori} eradication where drug formulations fail to deliver the minimum inhibitory concentration in gastric mucosa due to instability at low pH & short residence time in the stomach. The chitosan coated polymeric alginate beads containing sunflower oil can be given in hard gelatin capsule. It will be better to suggest administering the capsule after meal with taking one glass of water.