



Gastroretentive Drug Delivery System of Captopril and Hydrochlorothiazide Bilayer Tablet: Formulation, Optimization and *In Vivo* Evaluation.

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SUMMARY. The purpose of the present study was to develop and optimize floating-bioadhesive bilayer gastroretentive drug delivery system (GRDDS) exhibiting a unique combination of floatation and bioadhesion to prolong residence in the stomach using captopril (CP) and hydrochlorothiazide (HCTZ) as a model drug. Captopril being unstable in intestinal pH and HCTZ has specific absorption from duodenum and the first part of the jejunum and to a small extent in the stomach are suitable candidate for GRDDS. 3² factorial design was employed in formulating and optimizing the GRDDS for bilayer tablet of CP and HCTZ matrix tablet. The main effect and interaction terms were quantitatively evaluated using a mathematical model. The gastroretentive ability of the tablets was evaluated by X-radiographic studies in healthy human volunteer. The tablet releases CP and HCTZ for extended period up to 24 h in controlled manner. The predicted values agreed well with the experimental values and the results demonstrate the feasibility of the optimization methodology in the development of GRDDS. The tablet was buoyant for up to 16 h in human stomach. Development of once a day gastroretentive formulation of CP and HCTZ improves the patient compliance and bioavailability of drugs.

KEYWORDS: Captopril, Factorial design, Floating-bioadhesive tablet, Hydrochlorothiazide, X-ray studies.

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