Study of Omeprazole Stability in Aqueous Solution: Influence of Cyclodextrins

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Abstract:

Omeprazole (OME) is a prototype anti-secretory agent. This compound is very unstable, especially in acidic aqueous solutions. A stability indicating HPLC assay has been developed in order to investigate the effect of different factors on the stability of omeprazole. These factors included the pH with the tested values ranging from 6-10 and the temperature by monitoring the drug stability at 25, 37 and 40°C. The study was then extended to investigate the effect of cyclodextrins, namely beta-cyclodextrin (β-CD), dimethyl-beta-cyclodextrin (DMβ-CD), hydroxypropyl-beta-cyclodextrin (HPβ-CD) and maltosyl-beta-cyclodextrin (Mβ-CD) on the stability of omeprazole. The results showed the dependence of drug stability on the pH and temperature with the degradation being significant below pH 7 and at higher temperature. The degradation kinetics follows the first-order kinetics. The addition of different cyclodextrins accelerates the degradation of drug, and this effect was in the following manner: β-CD > DMβ-CD > Mβ-CD > HPβ-CD. The effect of different concentrations of HPβ-CD on the degradation of drug was also studied. It was noted that the degradation of drug depends on the concentration of HPβ-CD up to 1.0 mM; above this concentration the degradation was constant.

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