

**Effect of the drug-matrix on the stability of enalapril maleate in tablet formulations.**

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**Abstract**

The chem. stability of enalapril maleate in tablet dosage forms consisting of different formulation excipients was studied. The influence of various parameters such as heat, moisture, light and the drug-matrix was investigated. The degrdn. of enalapril maleate was followed by using an HPLC method, which was demonstrated to be specific, stability indicating, accurate and precise. The degrdn. kinetics of enalapril maleate in phosphate buffer solns. of pH values in the range of 2.2-10.5 were obsd. to be pseudo first order throughout the whole pH range studied. Enalapril maleate alone showed high stability for temp. under dry and humid conditions, however it became unstable when mixed with the drug-matrix in its tablet formulations and exposed to the same conditions. The pathway of degrdn. of enalapril maleate was found to be pH dependent. The extent of degrdn. of two different enalapril maleate tablet formulations (product A of a basic drug-matrix and product B of an acidic drug-matrix) has been investigated. The degree of degrdn. of the product with acidic matrix was significantly less than that of the basic matrix under same temp. and humidity conditions. Diketopiperazine and enalaprilat degradants were mainly assocd. with the degrdn. of the product with the acidic matrix and that with the basic matrix, resp. Dry enalapril maleate powder showed some photolysis, which was more significant with daylight (3.3%) compared with that under UV light (0.2%). Although the product with the acidic matrix showed some photolysis but the effect was not pronounced and the % recovery of enalapril was almost complete and within the acceptable exptl. errors. However, the product with the basic matrix showed almost no response for photolysis.