

Photodegradation Kinetics Studies of Enalapril Maleate by FTIR Spectroscopy

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Enalapril maleate is an effective prodrug for the treatment of renovascular hypertension and heart failure. The drug acts as angiotensin-converting enzyme inhibitor (ACE- inhibitor) and it is activated by hydrolysis to the active dicarboxylic acid, the enalaprilate. Several parameters such as heat, moisture and light are able to induce the prodrug degradation in five products, including the enalaprilate (hydrolytic degradation product) and diketopiperazine (DKP) (cyclization degradation product). The prodrug concentration and UV light-induced degradation kinetics of enalapril maleate were determined by FTIR using the KBr pellets technique. Identification of photoproducts and kinetic parameters of prodrug degradation were determined by calculations and analyses of areas and peak intensities of the IR bands. The enalapril maleate was identified by the band at 1751cm^{-1} attributed to vibrational normal mode of stretching of ester carbonyl group and the band at 1738 cm^{-1} attributed to vibrational normal mode of stretching of ester carbonyl group of DKP was used for the standardization of kinetics parameters of photodegradation. The standardized analysis method was used to compare four Brazilian commercial pharmaceutical formulations regarding the profile and kinetic of degradation referenced to a standard of high purity obtained from Aldrich-Sigma. Significant heterogeneity in the degradation profile and kinetics were found in the commercial tablets that alert for a risk for active principle loss promoted by manipulation and storage of the drugs. The results corroborated the FTIR spectroscopy technique as a simple, rapid and powerful tool for kinetic studies of drug stability and quality.