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"Pharmacodynamically evaluated bioequivalence of two preparations of Enalapril Maleate "

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Abstract:

The bioequivalence of two preparations of enalapril maleate (20 mg tablets) manufactured in Iran has been exploited in reference to a standard preparation (Xanef 20 tablets, MSD, Germany) in 14 healthy volunteers. Following oral dosing of a single tablet of each of test and standard products, as a randomized crossover design with 10-day washout intervals, the blood samples were collected in predetermined time points and using a synthetic substrate, Hippuryl-Histidy-Leucine (HHL), the release of hippuric acid from the substrate was determined as Angiotensin-Converting-Enzyme (ACE) activity of serum fractions. The percent of ACE inhibition in each sample was calculated and plotted against time, from which three pharmacodynamic parameters, i.e. Emax, tmax and AUC0-24 were derived. The results of statistical comparison of these parameters showed that both of the test preparations are bioequivalent with reference standard preparation.

Keywords:

Enalapril maleate ، ACE ، ACE inhibitors ، Clinical study

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