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Evaluation of the Bioequivalence of Two Tablet Formulations of Enalapril after Single Oral Administration to Chinese Healthy Volunteers

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***SUMMARY*. In this study, a simple, rapid and sensitive high performance liquid chromatography (HPLC) method is developed for determination of enalapril (ENP) in human plasma samples using carbamazepine as internal standard (IS). Sample preparation was accomplished through liquid-liquid extraction, and chromatographic separation was carried out on a ZORBAX SB-C18 (4.6 × 150 mm, 5 μm) at 70 °C. Mobile phase was composed of a mixture of acetonitrile-1 M sodium dihydrogen phosphate-water (27:20:53) at a flow rate of 1.0 mL/min. Wavelength was set at 286 nm. The method was successfully applied to a bioequivalence study of oral ENP drugs in Chinese healthy volunteers.**

RESUMEN. Se ha desarrollado un método de cromatografía líquida de alta resolución (HPLC) simple, rápido y sensible para la determinación de enalapril (ENP) en muestras de plasma humano usando carbamazepina como estándar interno (IS). La preparación de la muestra se llevó a cabo a través de extracción líquido-líquido y separación cromatográfica se realizó en una columna Zorbax SB-C18 (4,6 x 150 mm, 5 μm) a 70 °C. La fase móvil estuvo compuesta de una mezcla de acetonitrilo- fosfato monosódico 1 M-agua (27:20:53) a un caudal de 1,0 mL/min. La longitud de onda se fijó en 286 nm. El método se aplicó con éxito a un estudio de bioequivalencia de medicamentos orales conteniendo ENP en voluntarios sanos chinos.

KEY WORDS: Bioequivalence, Enalapril, HPLC.

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