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Development and Validation of a HPLC Method for Determination of Sertraline in Human Plasma and its Application to Bioequivalence Study

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***SUMMARY*. In this study, a simple, rapid and sensitive high performance liquid chromatography (HPLC) method is developed for determination of sertraline (SER) in human plasma samples using lorazepam as the internal standard (IS). Sample preparation was accomplished through liquid-liquid extraction method with ethyl acetate and normal hexane, and chromatographic separation was carried out on a ZORBAX SB-C18 (4.6 × 150 mm, 5 μm) at 50 °C. Mobile phase composed of a mixture of acetonitrile-0.15 M sodium dihydrogen phosphate-water (36:20:44) at flow rate of 1.0 mL/min. Wavelength was set at 240nm (0-6.4min) and 200nm (6.4-7.5min). The method was successfully applied to a bioequivalence study of oral SER drugs in Chinese healthy volunteers.**

RESUMEN. En este estudio se ha desarrollado un método de cromatografía líquida de alta resolución (HPLC) sencillo, rápido y sensible de para la determinación de sertralina (SER) en muestras de plasma humano, utilizando lorazepam como estándar interno (IS). La preparación de la muestra se realizó mediante extracción líquido-líquido con acetato de etilo y hexano normal, y la separación cromatográfica se llevó a cabo en una columna Zorbax SB-C18 (4,6 x 150 mm, 5 μm) a 50 °C. La fase móvil estuvo compuesta de una mezcla de fosfato monosódico 0,15 M-acetonitrilo-agua (36:20:44) a una velocidad de 1,0 mL/min. La longitud de onda se fijó en 240 nm (0-6.4min) y 200 nm (6,4-7.5min). El método se aplicó con éxito a un estudio de bioequivalencia de comprimidos de SER en voluntarios sanos chinos.

KEY WORDS: Bioequivalence study, HPLC, Human plasma, Sertraline.

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