



Comparative Pharmacokinetics of Cefspan and Ceforal-3 in Adult Human Healthy Female Subjects

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SUMMARY. Investigations regarding pharmacokinetics of two brands of cefixime 400 mg *i.e.* cefspan and ceforal-3 were carried out in healthy adult female volunteers. The drugs were administered orally after a washout period of seven days and concentration of cefixime in collected plasma samples was determined with high performance liquid chromatography method. One compartment open model was applied on plasma concentration versus time data using APO PC-Computer Program MW/PHARM version-3.02. Mean values of pharmacokinetic parameters of cefspan and ceforal-3 remained non significantly ($P > 0.05$) different from each other. Relative bioavailability based on AUC (27.12 ± 2.25 and 23.99 ± 1.07 $\mu\text{g}\cdot\text{h}/\text{mL}$) and C_{max} (2.24 ± 0.23 and 2.08 ± 0.16 $\mu\text{g}/\text{mL}$) for cefspan and ceforal-3, respectively, was found to be within the acceptable range for bioequivalence *i.e.* 80-125%. So ceforal-3, a test formulation, was found bioequivalent to the cefspan, a reference formulation and can replace each other in clinics.

RESUMEN. Se realizaron investigaciones sobre la farmacocinética de dos marcas de cefixima 400 mg (cefspan y ceforal-3) en voluntarias adultas sanas. Los fármacos se administraron oralmente después de un período de limpieza de siete días y se determinó la concentración de cefixima en muestras de plasma recogidas con un método de cromatografía líquida de alto rendimiento. Se aplicó un modelo abierto de un compartimento sobre la concentración de plasma frente a los datos de tiempo utilizando el APO PC-Computer Program MW / PHARM versión 3.02. Los valores medios de los parámetros farmacocinéticos de cefspan y ceforal-3 permanecieron no significativamente ($P > 0.05$) diferentes entre sí. La biodisponibilidad relativa basada en AUC ($27,12 \pm 2,25$ y $23,99 \pm 1,07$ $\mu\text{g}\cdot\text{h}/\text{mL}$) y C_{max} ($2,24 \pm 0,23$ y $2,08 \pm 0,16$ $\mu\text{g}/\text{mL}$) para cefspan y ceforal-3, respectivamente, se encontraron dentro del intervalo aceptable para la bioequivalencia, es decir 80-125%. Así, se encontró que el ceforal-3, una formulación de prueba, es bioequivalente al cefspan, una formulación de referencia, y puede sustituirse entre sí en clínica médica.

KEY WORDS: bioequivalence, ceforal-3, cefspan, females, pharmacokinetic.

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