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Bioequivalence Studies of 250 mg Ciprofloxacin Tablets in Pakistani Population

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***SUMMARY*. In third world countries bioequivalence study gained much importance due to the availability of comparative low cost of generics against multinational brand. Open, randomized, two period's crossover study of 250 mg Ciprofloxacin tablets were carried out in 12 healthy volunteers of Pakistani population. The plasma concentration of each volunteer was determined using validated HPLC technique. Each volunteer received 250 mg ciprofloxacin either standard or marketed brand. Compartmental pharmacokinetic parameters were estimated through Kinetica 4.4.1. The calculated parameters were further subjected to statistical analysis. Statistically no significant differences were noticed among the values of the two products in all the three major parameters C_{max} calculated, C_{max} observed, AUC_{0-t}, AUC_{total}, AUC_{last}, and T_{max}. Moreover, the 90% confidence intervals for the ratios of logarithmic transformed and non-transformed values of ciprofloxacin test over reference products were found to be 0.8-1.25 and 0.8-1.20, respectively, which were within the FDA bioequivalence limits. The analysis of variance (ANOVA) was applied in formulation, period, sequence and subject tested and satisfactory no significant difference was found. The two-one sided t test results proved the bioequivalence results of both brands.**

RESUMEN. En los países del tercer mundo, el estudio de bioequivalencia cobró mucha importancia debido a la disponibilidad del bajo costo comparativo de los genéricos contra la marca multinacional. Se llevó a cabo un estudio abierto, aleatorizado y cruzado de 250 mg de comprimidos de ciprofloxacina en dos periodos sobre 12 voluntarios sanos de la población pakistaní. La concentración plasmática de cada voluntario se determinó utilizando la técnica de HPLC validada. Cada voluntario recibió 250 mg de ciprofloxacina, ya sea de marca estándar o comercializada. Los parámetros farmacocinéticos compartimentales se estimaron mediante Kinetica (Versión 4.4.1). Los parámetros calculados fueron sometidos a análisis estadístico. Estadísticamente, no se observaron diferencias significativas entre los valores de los dos productos en los tres parámetros principales: C_{max} calculada, C_{max} observada, AUC_{0-t}, AUC_{total}, AUC_{last} y T_{max}. Además, los intervalos de confianza del 90% para las relaciones de valores logarítmicos transformados y no transformados de la prueba de ciprofloxacina con respecto a los productos de referencia, que fueron de 0.8-1.25 y 0.8-1.20, respectivamente, y estaban dentro de los límites de bioequivalencia de la FDA. El análisis de varianza (ANOVA) se aplicó en formulación, período, secuencia y sujeto evaluado y no se encontraron diferencias significativas. Los resultados de las pruebas t de dos caras probaron la bioequivalencia de ambas marcas.

KEY WORDS: bioequivalence study, ciprofloxacin tablets, compartmental studies, healthy volunteers, HPLC.

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