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A two-way crossover bioequivalence study of cefadroxil after single oral administration of droxil and ultracef suspensions to 24 healthy human volunteers

F A Mohammed

Albaha University, Kingdom of Saudi Arabia

This study presents a two-way, single oral dose, two-weeks washout, crossover bioequivalence study carried out on 24 human volunteers to compare the bioavailability of two locally marketed pharmaceutical products containing cefadroxil, namely, droxil suspension (Test product commercially marketed suspension containing 500 mg of cefadroxil per 10 ml, produced by the United Pharmaceutical Manufacturing Company, Amman, Jordan) and ULTRACEF® suspension (Reference product, commercially marketed suspension containing 500 mg of cefadroxil per 10 ml, produced by Bristol Laboratories, USA). The two products were administered to 24 healthy human volunteers under fasting condition. Following drug administration, venous blood samples (8 ml) for determination of cefadroxil were collected pre-dose (0 hours) and at 0.25, 0.5, 0.75, 1, 1.25, 1.50, 1.75, 2, 2.5, 3, 4, 5, 6, 8 and 10 hours after drug administration. Plasma was separated immediately by centrifugation and stored at -20°C until analysis. Cefadroxil analysis was carried out by a fully developed HPLC assay procedure. The results obtained revealed that the two products were bioequivalent as indicated by the absence of statistical differences in the plasma concentrations or Pharmacokinetics parameters of the two products. The two products therefore can be alternatively prescribed.

fergmed@yahoo.com