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Bioequivalence and pharmacokinetics of chlorpheniramine in healthy human volunteers.

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Source

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Abstract

This study was carried out to evaluate the bioavailability of a new regular release tablet formulation of chlorpheniramine (CPA) (Histop) relative to a reference formula (Piriton) using 13 human healthy volunteers. Each one received the two formulations as two 4 mg tablets in a two-way double-blind, crossover study. The concentration of CPA was measured with a sensitive high performance liquid chromatography (HPLC). The geometric mean for the area under the curve up to the last concentration (AUC_{0-t}), to infinity (AUC_{0-∞}) and the maximum concentration (C_p max) were 316.5, 315 + 439.8, 431.2 (ngh/ml) and 22, 20.5 (ug/ml) for the test (T) and reference (R) formulations, respectively. The parametric 90% confidence intervals of T/R ratio of the above parameters were within the bioequivalence acceptable range of 80-125%. The mean time to the maximum concentration T_{max} (h) were 2.5 and 2.08 for the two formulations respectively and the parametric 90% confidence intervals of the T_{max} difference (T-R) were in the range of -0.26-1.14 h, with point estimate of 0.44 h. The two formulations were found to be bioequivalent by the Schuirmann two one-sided t-test. Based on the pharmacokinetic results obtained frequent (ie, Q 4-6 h) CPA daily dosing may not be required particularly for the adults because of its long elimination half-life.

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