Pharmacokinetics and Bioequivalence study of a generic desloratadine tablet formation in healthy male volunteers

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摘要

Abstract

The pharmacokinetic profiles and relative bioavailability of desloratadine (CAS 100643-71-8, Denosin as test and another commercially available preparation as reference) tablets from two different pharmaceutical manufacturers were carried out. A single oral dose (10 mg/2 tablets) of desloratadine was administered to 8 healthy young Chinese males in a completely double-blind cross-over design with a two-week washout period between each dose. Plasma samples were obtained before and at various appropriate intervals after dosing up to 120 h. The plasma concentrations were then analyzed by a liquid chromatography/tandem mass spectrometric (LC/MS/MS) method. The limit of quantitation of this LC/MS/MS method was 0.05 ng/mL. The coefficients of variation of the within-day and between-day calibration curves (n = 6) range from 0.05 ng/mL to 10 ng/mL and were less than 10%. The accuracy of this method was verified. Values for the area under the plasma concentration-time curve (AUC), peak concentration (Cmax), time to peak concentration (Tmax), elimination rate constant, half-life, oral clearance were estimated and compared for each preparation. By ANOVA, 90% confidence interval, Mann-Whitney test, and paired t-test, the two desloratadine products can be considered bioequivalent for both the extent and the rate of absorption