Bioavailability comparison between a Chilean generic preparation of ambroxol and the original product Bioequivalencia de una formulación nacional de ambroxol

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Objectives: To assess the relative bioavailability of two oral formulations of ambroxol commercialized in Chile, a generic syrup and the original product, Mucosolvan R from Boehringer Ingelheim. Methods: A randomized, cross-over and double blind study was performed in twelve healthy volunteers who received a single oral dose of either Mucosolvan (90 mg) or the generic formulation with at least a 14 day washout period between each single dose. Multiple blood samples were collected after each dose, the plasma ambroxol concentrations were determined by a validated High Performance Liquid Chromatography assay. Results: The 95% confidence intervals for all parameters were within the accepted range of 80-125% for bioequivalence, suggested by the US FDA. Non statistically significant differences were found in the mean parameters of bioequivalence: mean peak concentration (C max), area under the curve calculated from time zero to a determined time (AUC 0-t), and area under the curve calculated