



Bioequivalency study for inhaled drugs: a pharmacodynamic approach

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The study was performed to evaluate the pharmacodynamics response of test formulation of formoterol 6 mcg associated with 200 mcg budesonide (Test formulation from Biosintética Farmacêutica Ltda and reference formulation from AstraZeneca, Brazil) in 27 volunteers of both sexes. The study was conducted open randomized 2 period crossover balanced design with a 36 days wash out period between the doses. The formoterol and budesonide were analyzed by evaluation of the pharmacodynamic test and reference formulations was performed by Spirometry comparing the process to prevent wheezing illness induced by methacholine. The mean ratio of parameters AUC_{0-t} and 90% confidence intervals of correspondents were calculated to determine the pharmacodynamics response. Geometric mean for the test and reference formulation of formoterol with budesonide in the form of dry powder in capsule was AUC_{0-t} ratio (test/reference: 101.70% [98.53% - 104.98%]). Considering the confidence intervals (90%) of the ratios between the geometric means for the test and reference formulation of formoterol with budesonide in the form of dry powder in capsule parameter AUC_{0-t} , which, being a pharmacodynamic study in which intervals for determination of therapeutic equivalence are not yet established and that the limits of the confidence interval of the parameters studied are within the range established in 1170 by RE (ANVISA) for pharmacokinetic parameters, concluded that the formulation of formoterol with budesonide in the form of dry powder in a capsule being marketed by Biosintética Pharmaceuticals Ltd. is therapeutically equivalent to about pharmacodynamic evaluation to the formulation of Symbicort[®] produced by AstraZeneca Brazil.

Biography

Eduardo Abib Junior has completed his Ph.D studies from University of Campinas (UNICAMP). He is the director of Scentryphar, a Clinical Research service organization and President Brazilian Association of Bioavailability and Bioequivalence Centers. He has published more than 40 papers in reputed journals and serving as an editorial board member of repute. Participated in more than 08 Committees examinations theses, Invited Speaker and Instructor in the area of clinical research.