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Bronchoprovocation study of Albuterol inhalation on asthma patients: A Pharmacodynamic Bioequivalence Study

Nailesh Patel and **Rashmin Patel**
Department of Pharmacology, S.K. Patel College of Pharmaceutical Education and Research, Ganpat University, Mehsana, Gujarat, India.

Objective: The main objective of the study is to determine the clinical endpoints bioequivalence between Test and Reference Albuterol inhalation formulation & to find out the superiority of test over placebo.

Methods: The study was conducted in asthma patients of either gender with methacholine challenge. Patients with known surgical histories, known and suspected cases of allergies and pregnant woman's were excluded from this study. Total 260 patients were included. The design of the study was single-dose, double-blind, double dummy, randomized, crossover study with washout of at least 24 hours.

Result: Post-dose PC20 or PD20, which are the provocative concentration or dose, respectively, of the methacholine challenge agent required to reduce the forced expiratory volume in one second (FEV1) by 20% following administration of differing doses of albuterol (or placebo) by inhalation is 15.84±0.02. The 20% reduction in FEV1 is determined relative to the saline FEV1 measured before the placebo or albuterol administration. A significant dose-effect relationship was present ($p < 0.0001$). Deviation from parallelism of the test and reference dose-response curves ($p = 0.95$) and differences in overall mean response between the two formulations ($p = 0.68$) were not significant. The calculated 90% CI was 78.86-144.87% for FEV1. There were no serious adverse events observed during the study.

Conclusion: The 90% CI for the relative bioavailability (F) falls within the defined bioequivalence limit, i.e., 67.00-150.00%. Hence, it is concluded that Albuterol test formulation is bioequivalent to reference Albuterol formulation.

Biography

Dr. Nailesh Patel is working at S.K. Patel College of Pharmaceutical Education and Research, Ganpat University, Mehsana, Gujarat, India.

ptlnailesh@yahoo.co.in

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