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Bioequivalence of Salmeterol xinafoate/Fluticasone propionate HFA pMDI of two different strengths (25/250 mcg and 25/125 mcg per actuation) in healthy volunteers

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Salmeterol xinafoate and fluticasone propionate has been shown to be effective and well tolerated in the treatment of asthma. The aim of these studies was to determine the bioequivalence between test and reference formulations of salmeterol xinafoate/fluticasone propionate HFA pMDI in healthy volunteers. A total of 4 pharmacokinetic studies were conducted, 2 with the higher strength (25/250 mcg per actuation) and 2 with the lower strength (25/125 mcg per actuation) of the test and reference formulation. All studies were single dose, randomized, crossover studies with a minimum washout period of 14 days. Two of the four studies (for each strength) also evaluated pulmonary deposition by blocking gastrointestinal absorption (GI) using charcoal blockade. Safety evaluations included monitoring adverse events and vital signs as well as clinical laboratory assessments. Plasma concentrations of salmeterol xinafoate and fluticasone propionate were determined using a validated LC-MS/MS method. In the studies without charcoal blockade, the 90% CI for Cmax and AUC0-t for 25/250 mcg salmeterol was 83.44-100.29, and 104.08-120.08 respectively, for 25/125 mcg it was 88.33-106.08 and 100.49-114.88 respectively. Similarly, in the studies with charcoal blockade, the 90% CI for Cmax and AUC0-t for 25/250 mcg salmeterol was 94.10-113.20, and 96.44-116.69 respectively, for 25/125 mcg it was 100.70-115.72 and 104.99-122.70 respectively. For fluticasone, the 90% CI for Cmax and AUC0-t for 25/250 mcg was 91.08-105.07 and 99.86-115.61 respectively and for 25/125 mcg, it was 87.04-105.03 and 85.38-103.42 respectively. Since the 90% CI for Cmax and AUC0-t for both salmeterol and fluticasone were within the 80–125% interval in all the studies, it was concluded that test and reference formulations of salmeterol xinafoate/fluticasone propionate HFA pMDI are bioequivalent in their rate and extent of absorption with and without charcoal blockade for both the strengths.

Biography

Muneesh Garg has completed his MD (Physician) from Dagestan State Medical Academy, Russia and MD (Pharmacology) from Government Medical College, Patiala, Punjab, India. He has more than 18 years of experience in academia, and clinical research. He is the Principal Investigator of Sitec Labs Pvt Ltd., Navi Mumbai, India, for more than 11 years and has completed about 1000 BA/BE studies. He has published many research papers in reputed journals.

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