Muneesh Garg et al., J Bioanal Biomed 2017, 9:4, (Suppl)
DOI: 10.4172/1948-593X-C1-030

Assessment of bioequivalence between two formulations of Salmeterol xinafoate/Fluticasone propionate HFA pMDI 25/250 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. Our research aimed to determine the bioequivalence between two formulations (test and reference) of salmeterol xinafoate/fluticasone propionate HFA pMDI 25/250 mcg per actuation with and without charcoal blockade. Study-1 was a single dose, randomized, 4-period, 2-sequence, laboratory-blinded, crossover replicate design conducted in 42 healthy volunteers under fasting conditions with concurrent oral charcoal administration (to block gastrointestinal absorption). Study-2 was a single dose, randomized, 2-period, 2-sequence, laboratory-blinded, crossover design conducted in 74 healthy volunteers under fasting conditions without concurrent oral charcoal administration. Both the studies had a minimum washout period of 14 days. Blood samples were collected up to 18 hours post-dose and 36 hours post-dose for pharmacokinetic profiling for study-1 and 2 respectively. 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. The 90% CI of the difference between the test and reference for salmeterol xinafoate was 94.10-113.20, and 96.44-116.69 for Cmax, and AUC0-t respectively in study-1. The 90% CI of the difference between the test and reference for salmeterol xinafoate was 83.44-100.29 and 104.08-120.08 and for fluticasone propionate was 91.08-105.07, and 99.86-115.61 for Cmax, and AUC0-t respectively in study-2. Since the 90% CI for Cmax and AUC0-t was within the 80-125% interval in both the studies, it was concluded that test and reference formulations of salmeterol xinafoate/fluticasone propionate HFA pMDI 25/250 mcg per actuation are bioequivalent in their rate and extent of absorption with and without charcoal blockade.

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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