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Bioequivalence of Ipratropium Bromide HFA pMDI 20 µg/actuation in healthy volunteers with and without charcoal blockade and with spacer device

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Ipratropium Bromide is a short-acting anti-cholinergic bronchodilator used in the management of chronic obstructive pulmonary disease. The aim of these three studies was to determine the bioequivalence of test and reference formulations of ipratropium bromide HFA pMDI 20 µg/ actuation with and without charcoal blockade; and with spacer device. Study-1 was single dose, randomized, 4-period, 2 sequences, laboratory-blinded, crossover and replicate design conducted in 90 healthy volunteers under fasting conditions with concurrent oral charcoal blockade. Study-2 was single dose, randomized, 2-period, 2 sequences, laboratory-blinded and crossover design conducted in 24 healthy volunteers under fasting conditions without concurrent oral charcoal blockade. Study-3 was single dose, randomized, 2-period, 2 sequences, laboratory-blinded and crossover design conducted in 64 healthy volunteers under fasting conditions with AeroChamber Plus valved holding chamber. Blood samples were collected up to 24 hours post-dose for pharmacokinetic profiling. Safety evaluations included monitoring adverse events and vital signs as well as performing clinical laboratory tests. Plasma concentrations of ipratropium were determined with a validated LC-MS/MS method. The 90% CI of ipratropium were 91.30-99.91, and 90.42-97.77; 87.33- 121.30, and 88.94-120.34; 87.21-99.83, and 91.66-97.94 for C_{max}, and AUC_{0-t} for study-1, study-2, and study-3 respectively. Since the 90% CI for C_{max} and AUC_{0-t} were within the 80-125% interval, it was concluded that test and reference formulations of Ipratropium Bromide HFA pMDI 20 µg per actuation are bioequivalent in their rate and extent of absorption with and without charcoal blockade; and with spacer device.

Biography

Muneesh Garg has completed his MD (Physician) from Dagestan State Medical Academy, Russia in 1997 and MD in Pharmacology from Government Medical College, India in 2004. He has more than 17 years of experience in Clinical Practice and Clinical Research. He is the Principal Investigator of Sitec Labs Pvt. Ltd., India, for more than 10 years. He has published many research papers in reputed journals.

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