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Bioequivalence of Fluticasone Propionate HFA pMDI 250 mcg per actuation in healthy volunteers with and without spacer device

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Fluticasone propionate given by inhalation is used for prophylactic treatment for asthma of all severities. The recommended dose in adults and children over 16 years is 100 to 1,000 micrograms twice daily, usually as two twice daily inhalations. Flixotide Evohaler may be used with a volumatic spacer device by patients who find it difficult to synchronize aerosol actuation with inspiration of breath. FlixotideR 250 EvohalerR (containing fluticasone propionate 250 mcg per actuation) is approved for marketing in Europe manufactured by Glaxo Wellcome Production, France. Cipla Ltd., India has developed a generic formulation of fluticasone propionate HFA pMDI 250 mcg/actuation. Cipla Ltd was interested in obtaining the marketing authorization for fluticasone propionate HFA pMDI 250 mcg/actuation in European Union. Therefore, two PK bioequivalence studies were submitted to demonstrate therapeutic equivalence between the test and the reference formulation of fluticasone propionate HFA pMDI 250 mcg/actuation with and without a spacer device. Study-1 was a single dose, randomized, 4-period, 2-sequence, laboratory-blinded, crossover replicate design conducted in 32 healthy volunteers under fasting conditions without volumatic spacer. Study-2 was a single dose, randomized, 2-period, 2-sequence, laboratory-blinded, crossover design conducted in 28 healthy volunteers under fasting conditions with volumatic spacer. The 90% CI of fluticasone propionate for Cmax and AUC0-t were within the 80–125% interval in both the studies, so it was concluded that test and reference formulations of fluticasone propionate HFA pMDI 250 mcg per actuation are bioequivalent in their rate and extent of absorption with and without a spacer device. In this presentation data of both the studies will be presented.

Biography

Dr Muneesh Garg has completed his MD (Physician) from Dagestan State Medical Academy, Russia and MD (Pharmacology) from Goverment 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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