Pharmacokinetics and Bioequivalence of Two Fluticasone Propionate Aerosols Delivered by Metered Dose Inhaler in Healthy Male Chinese Volunteers

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SUMMARY. To assess the bioequivalence of new generic fluticasone propionate (FP) aerosol with the reference FP aerosol in healthy Chinese male volunteers. An open-label, randomized-sequence, single-dose, double crossover study was conducted. Blood samples were collected at baseline and 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 8, 12, 24, 36, and 48 h after a single dose of 500 μg FP test or reference. Concentrations of FP were determined by using a validated LC-MS/MS method. Drug and Statistics 2.1.1 software was used to calculate the pharmacokinetics parameters and assess bioequivalence of the two formulations. The main pharmacokinetics parameters for the test and reference were as follow: t1/2 was (8.38 ± 1.76) h and (8.06 ± 1.16) h; T_max was (1.60 ± 0.26) h and (1.63 ± 0.28) h; C_max was (74.70 ± 11.06) pg/mL and (71.52 ± 12.68) pg/mL; AUC_{0-t} was (630.34 ± 220.76) pg·h/mL and (595.53 ± 204.14) pg·h/mL; AUC_{0-∞} was (795.99 ± 259.22) pg·h/mL and (776.05 ± 320.14) pg·h/mL. The mean ratios (test:reference) for C_max, AUC_{0-t}, and AUC_{0-∞} were 107.5 ± 18.3%, 101.7 ± 22.2%, and 104.6 ± 37.1%, respectively. No significant (p > 0.05) differences in pharmacokinetic parameters were found between preparations, treatments and periods. This single-dose study in healthy Chinese volunteers was shown that the FP test and reference were bioequivalent.