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A bioequivalence study of two Nicotine 2mg Lozenge formulations in healthy adult Indian human male smoker subjects

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Nicotine Lozenges are used to aid smokers wishing to quit smoking or reduce prior to quitting. The aim of this study was to determine the bioequivalence of a test and reference formulation of Nicotine 2 mg Lozenge. This single dose, randomized, 2-period, 2 sequence, laboratory-blinded, crossover design study was conducted in 21 healthy adult Indian human male smoker subjects under fasting conditions with a washout period of 7 days. Study formulations were administered after a 10-hour overnight fast. Blood samples for pharmacokinetic profiling were taken post-dose up to 16 hours. Safety was evaluated through the assessment of adverse events, and laboratory tests. Plasma concentration of Nicotine was determined with a validated LC-MS/MS method. Bioequivalence between the products was determined by calculating 90% confidence intervals (90% CI) for the ratio of C_{max} and AUC_{0-t} values for the test and reference products, using logarithmic transformed data. The 90% confidence intervals of C_{max} and AUC_{0-t} for Nicotine were 96.16-119.10 and 92.16-111.51 respectively. Since the 90% confidence intervals for C_{max} and AUC_{0-t} were within the 80-125% interval, it was concluded that the two formulations of Nicotine 2 mg Lozenge are bioequivalent in their rate and extent of absorption.

Biography

Muneesh Garg has completed his MD Physician from DSMI, Russia and MD Pharmacology from BFUHS Faridkot, Punjab, India. He is the Principal Investigator of Sitec Labs Pvt. Ltd., Navi Mumbai, India, a premier contract research organization.

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