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An accurate, Rapid and Sensitive LC-MS-MS Method for Quantification of Amlodipine in Human Plasma: Application to a Bioequivalence Study

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SUMMARY*. An efficient liquid chromatography-tandem mass spectrometry method was developed for quantification of amlodipine in human plasma with gliclazide as internal standard. The analytes were extracted with one-step liquid-liquid extraction, and separated using a C_{18} column (2.1 × 100 mm, 3.5 μm) within the totally runtime of 4.2 min. The linear range for amlodipine in human plasma was 0.05-15 ng/mL. The specificity, matrix effect, absolute extraction, accuracy, dilution effect and stability were in accordance to US Food and Drug Administration guidlines. This method was applied to bioequivalence study of amlodipine besylate tablets. An open-label, two-way crossover, randomized-sequence study of single-dose oral 10mg amlodipine besylate tablets were conducted in healthy Chinese male volunteers. 90% confidence intervals for the mean AUC_{0-t}, $AUC_{0-\infty}$ and Cmax ratios (test/reference) were 99.7-105.9%, 99.8-107.3%, and 98.6-108.8%. Two one-side t-test and analysis with 90% confidence intervals of variance for the AUC_{0-t}, $AUC_{0-\infty}$ and C_{max}, nonparametric-test for T_{max} suggested the two products were bioequivalent.

KEY WORDS: Amlodipine, Bioavailability, Bioequivalence, Human plasma, LC-MS-MS.

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