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LC-MS法评价两种苯磺酸氨氯地平片的人体生物等效性 [点此下载全文](#)

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摘要:

目的:建立LC-MS法测定人体血浆中苯磺酸氨氯地平的药物浓度,并进行两种制剂的生物等效性评价。方法:20例健康受试者单剂量交叉口服10 mg苯磺酸氨氯地平供试制剂或参比制剂后,采用LC-MS测定人体血浆中不同时间点苯磺酸氨氯地平的浓度,计算其药代动力学参数和相对生物利用度,评价两制剂的生物等效性。结果:苯磺酸氨氯地平供试制剂和参比制剂主要药代动力学参数如下:C_{max}分别为(6.21±1.88)、(6.03±1.08) ng/ml, AUC₀₋₁₂₀分别为(250.68±52.61)、(246.14±52.11) ng·h/ml, T_{max}分别为(6.0±2.3)、(6.1±2.5) h, t_{1/2}分别为(40.45±6.68)、(43.74±9.05) h。本方法在0.1-20.0 ng/ml浓度范围内线性关系良好。最低可定量浓度为0.1 ng/ml,两制剂主要药代动力学参数经统计学检验无显著性差异。结论:本方法简单、快速、准确,两种制剂具有生物等效性。[

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Liquid chromatography-mass spectrometry in evaluation of bioequivalence of two kinds of amlodipine besylate tablets [Download Fulltext](#)

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Abstract:

Objective: To establish a liquid chromatography-mass spectrometry (LC-MS) method for determining the concentration of amlodipine besylate in human plasma and to evaluate the bioequivalence of 2 kinds of amlodipine besylate tablets. Methods: Twenty healthy male volunteers were enrolled into a single crossover study. A single dose of the suspension equivalent to 10 mg amlodipine besylate or a reference preparation was given in a crossover way. The plasma concentrations of amlodipine besylate were determined by LC-MS method in the volunteers at different time points; the pharmacokinetic parameters and relative bioavailability were calculated and the bioequivalence of the 2 preparations were evaluated. Results: The pharmacokinetic parameters for experimental and the reference preparations were: C_{max} (6.21 ± 1.88) vs (6.03 ± 1.08) ng/ml; AUC₀₋₁₂₀ (250.68 ± 52.61) vs (246.14 ± 52.11) ng h/ml; T_{max} (6.0 ± 2.3) vs (6.1 ± 2.5) h; t_{1/2} (40.45 ± 6.68) vs (43.74 ± 9.05) h, respectively. The linear range of the present method was 0.1-20.0 ng/ml; the lowest detectable concentration of amlodipine besylate was 0.1 ng/ml. There was no significant difference in pharmacokinetic parameters between the 2 tablets. Conclusion: The present method is simple to use, fast, and accurate. The 2 preparations of amlodipine besylate are bioequivalent. [

Keywords: [amlodipine](#) [benzenesulfonates](#) [chromatography](#) [high pressure liquid](#) [spectrum](#) [analysis](#) [mass](#) [pharmacokinetics](#) [biological availability](#)

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