

论文

多剂量口服5-单硝酸异山梨酯缓释片及普通片的药代动力学和生物利用度研究

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摘要:

对10名健康男性受试者连续6d多剂量交叉poIS-5-MN缓释片和普通片的药代动力学性质和相对生物利用度进行了研究。结果表明:IS-5-MN缓释片和普通片的T_{max}分别为5.0h和1.4h(P<0.05),前者的缓释效果十分明显;AUC经对数转换后的多种统计分析表明,IS-5-MN缓释片(40mg)与IS-5-MN普通片(20mg×2)生物等效;IS-5-MN缓释片的相对生物利用度为108.95%;IS-5-MN缓释片和普通片的C_{min}分别为74.20ng·ml⁻¹和134.42ng·ml⁻¹(P<0.05),而两种制剂的其他药代动力学参数如C_{max},AUC²⁴₀,AUC[∞]₀,Ke,T_{1/2}以及波动系数(FI)等均无显著性差异(P<0.05)。多次给药后两种制剂都无明显的蓄积。

关键词: 5-单硝酸异山梨酯 药代动力学 生物利用度 缓释片

MULTIPLE DOSE PHARMACOKINETIC AND BIOAVAILABILITY STUDIES OF ORAL SUSTAINED RELEASE AND CONVENTIONAL FORMULATIONS OF ISOSORBIDE-5-MONONITRATE IN HEALTHY VOLUNTEERS

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Abstract:

The pharmacokinetics of a new sustained release tablets (40 mg, qd) of isosorbide-5-mononitrate (IS-5-MN) was investigated together with a conventional preparation (20 mg, bid) after multiple oral administration in ten healthy human subjects using an open, randomized two-way crossover experimental design. Based on three statistical analyses of the area under the plasma concentration time curve (AUC), the two tablet formulations are judged to be bioequivalent (P>0.1), with a relative bioavailability of 108.95% for the IS-5-MN sustained release formulation. Pharmacokinetic data showed that the sustained release formulation reached mean peak plasma levels significantly later and lower minimum plasma concentration (C_{min}), compared with the conventional preparation. But no statistically significant difference was found for other pharmacokinetic parameters including peak plasma levels (C_{max}), AUC, elimination constant (Ke), elimination half-life (T_{1/2}) and fluctuation index (FI) between the two preparations (P>0.05).

Keywords: Sustained release tablets Pharmacokinetics Bioavailability Isosorbide-5-mononitrate

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2. 杨丽莉;袁倚盛;赵飞浪.5-单硝酸异山梨酯血药浓度测定及其在人的药代动力学[J]. 药学报, 1997,32(10):

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