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论文

硫酸沙丁胺醇渗透泵控释片的人体药代动力学与生物利用度

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摘要:

目的:研究自制硫酸沙丁胺醇渗透泵控释片与进口控释片的人体药代动力学与生物利用度。方法:利用高效液相色谱荧光检测法,采用交叉实验设计对本品和进口硫酸沙丁胺醇控释片进行人体生物利用度对照研究。结果:硫酸沙丁胺醇控释片与进口硫酸沙丁胺醇控释片的血药浓度曲线下面积AUC 分别为(63.67 ±10.37)ng·h·mL^{-1}和(60.21 ±11.95) ng·h·mL^{-1},最大血药浓度C_{max} 分别为(8.60 ±1.93) ng·mL^{-1} 和(8.20 ±1.40)ng·mL^{-1},达峰时间T_{max} 分别为(6.3 ±1.0) h 和(6.8 ±1.3) h,多剂量给药达稳态时血药浓度波动系数FD 分别为1.09 ±0.23 和1.14±0.25。结论:经方差分析和双单侧检验,两种制剂生物等效。

关键词: 硫酸沙丁胺醇 渗透泵 相对生物利用度 药代动力学

STUDY ON THE HUMAN PHARMACOKINETICS AND RELATIVE BIOAVAILABILITY OF SALBUTAMOL SULFATE ORAL OSMOTIC PUMP CONTROLLED TABLETS

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Abstract:

AIM: To prepare salbutamol sulfate osmotic pump controlled tablet and study the pharmacokinetics and relative bioavailability of two kinds of salbutamol sulfate oral osmotic pump controlled tablets in healthy volunteers. METHODS: Tablet core, made mainly of sodium chloride, was coated with cellulose acetate and then drilled by laser to make osmotic pump controlled tablets. HPLC method was employed to detect the plasma drug concentration in 12 healthy volunteers. Two one sided tests and analysis of variance were performed to evaluate the bioequivalence of the two formulations. RESULTS: The pharmacokinetic parameters of self prepared controll tablets and imported tablets were listed below: T_{max} were (6.30±1.0) h and (6.8±1.3) h,C_{max} were (8.60±1.93) ng·mL^{-1} and (8.20±1.40) ng·mL^{-1}, AUC were (63.67±10.37) ng·h·mL^{-1} and (60.21±11.65) ng·h·mL^{-1} respectively. For multi dose administration, the fluctuation degree (FD) were 1.09±0.23 and 1.14±0.25 respectively. CONCLUSION: The two formulations were found to be bioequivalent.

Keywords: osmotic pump relative bioavailability pharmacokinetics salbutamol sulfate

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