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论文

罗红霉素片剂生物利用度的比较研究

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摘要:

为比较不同剂型罗红霉素的生物利用度,用微生物管碟检定法(藤黄微球菌CMCC(B)28001)测定了10名男性健康受试者口服罗红霉素分散片(制剂A)和罗红霉素片(制剂B)后不同时间血浆中活性药物的浓度,绘制了血药浓度—时间曲线。结果表明,受试者交叉口服含罗红霉素150mg的制剂A和制剂B后,血浆T_{max}分别为1.7±0.9和3.7±1.6h,C_{max}分别为4.97±1.17和2.04±1.26μg·ml^{-1},$AUC_{0\rightarrow\infty}$分别为62.2±11.9和35.0±16.9μg·h·ml^{-1}。以制剂A为参比,制剂B中罗红霉素的相对生物利用度仅为59.8%±32.6%,两种制剂的药物吸收程度有显著差异(P<0.01)。初步分析提示,罗红霉素在胃中的迅速溶出是保证其片剂生物利用度的关键之一。

关键词: 罗红霉素 普通片 分散片 生物利用度

COMPARISON OF ROXITHROMYCIN BIOAVAILABILITY OF A CONVENTIONAL AND A DISPERSIBLE TABLET FORMULATION

Zhong Dafang ; Huang Haihua ; Wang Aimin ; Tian Lei ; Lei Xiaoyan and Zhang Jiwen

Abstract:

Following oral administrations of a single dose of 150 mg roxithromycin dispersible tablet (formulation A, a new formulation for clinical trial) and conventional tablet (formulation B, purchased from the market) to each of 10 healthy male volunteers in a randomized crossover design, the plasma levels of active drug at different times were determined by a microbial assay with *Micrococcus luteus* CMCC (B) 28001 and the plasma concentration—time profiles were obtained. The T_{max} values of formulation A and B obtained were 1.7±0.9 and 3.7±1.6 h, the C_{max} values were 4.97±1.17 and 2.04±1.26 μg·ml^{-1} and the $AUC_{0\rightarrow\infty}$ values were 62.2±11.9 and 35.0±16.9 μg·h·ml^{-1}, respectively. Surprisingly, the relative bioavailability of formulation B was found to be only 59.8%±32.6% (P<0.01). The low bioavailability of the latter formulation was attributed to poor release of roxithromycin in the gastric site, which was proposed as a key factor to influence drug absorption. Other related factors were also discussed.

Keywords: Conventional tablet Dispersible tablet Bioavailability Roxithromycin

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