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论文

消炎痛缓释胶囊的生物利用度研究

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摘要:

消炎痛普通制剂口服吸收迅速,可出现不必要的高血药浓度,导致不良反应。为此我们对三种消炎痛缓释胶囊 (A,B,C)和一种常用片剂(D)作了体外溶出试验和体内生物利用度比较。胶囊制剂由丙烯酸类树脂材料 E_{30} D包衣的药物小丸制成,其体外溶出行为显示缓慢释放图象。在8名成年男性交叉实验中,不同胶囊制剂和普通片剂之间的 Tmax,Cmax和 $AUC_{0\sim12h}$ 经方差分析无统计学差异,但是在给药后4至12小时的血清浓度一时间曲线,均比普通片剂高而平滑。在第12小时,三种胶囊产生的血清浓度显著高于普通片剂(P<0.1)。根据体外溶出行为和体内生物利用度发现 T_{50} 或Tmax和包衣厚度呈良好线性关系。

关键词: 消炎痛 缓释胶囊 包衣 溶出速率 生物利用度

STUDIES ON BIOAVAILABILITY OF SUSTAINED RELEASE INDOMETHACIN CAPSULES

Li Duan; Yang Xiang-Yuan; Wang Jin-Ping; Wang Yong-Ming; Shan Jie; Zhang Hong-Lu; Bai Yao-Zhou: Tao Xiao-Hua: and Mo Shan-Yuan

Abstract:

In order to avoid high initial peak of the commercially available indomethacin formulation and increase the interval between dosages, comparison of three sustained release indomethacin capsules on pellet coated with Eudragit- $E_{30}D$ and a commercially available tablet was carried out by testing *in vitro* the dissolution behaviour and *in vivo* bioavailability. Dissolution studies on three batches of pellet capsules with varying drug to coat material ratios (mg/cm²) exhibited a sustained release pattern. In vivo serum level for 8 adult male subjects of randomized crossover design showed no statistical difference in bioavailability between different capsule formulations and a tablet formulation available on the market. However, these three capsule formulations demonstrated a higher and smoother serum concentrationtime curves than that of the tablet formulation from 4 to 12 h following a single dose (50mg). The serum level of three capsule formulations was significantly higher than that of the tablet formulation (P<0.1) at the 12th h respectively. In vitro dissolution behaviour and *in vivo* bioavailability, the linear relationships were found between T_{50} or $T_{\rm max}$ and drug to coat material ratios.

Keywords: Sustained release capsule Pellet Dissolution behaviour Bioavailability Indomethacin

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