

### 论文 酮洛芬缓释片与常释片在健康受试者的药代动力学及生物利用度

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#### 摘要:

目的: 酮洛芬缓释片与常释片单次给药的生物利用度和多次给药的峰谷浓度波动大小。方法: 采用以萘普生(naproxen)为内标的HPLC测定方法,测定健康男性受试者按交叉试验单剂量和多剂量服用酮洛芬缓释片和常释片后的血中酮洛芬浓度。结果: 单剂量服用酮洛芬缓释片和常释片后,常释片的C<sub>max</sub>显著高于缓释片(P<0.01),缓释片给药后的T<sub>max</sub>延迟,t<sub>1/2ke</sub>显著延长,相对生物利用度为97.13%。缓释片在稳态时的C<sub>min</sub>为0.401μg·mL<sup>-1</sup>,而常释片为0.190μg·mL<sup>-1</sup>(P<0.01)。在稳态时缓释片的峰谷浓度波动度(DF)、峰谷比(PTR)都显著小于常释片,说明缓释片的峰谷浓度波动程度优于常释片。结论: 经统计学检验表明这两种制剂具有生物等效性,该缓释片具有峰谷浓度差异小,波动幅度小的特点,显示出缓释特征。

关键词: 酮洛芬 HPLC 单次和多次给药 药代动力学 生物利用度

### COMPARISON OF PHARMACOKINETICS AND BIOAVAILABILITY OF REGULAR TABLETS KETOPROFEN AND ITS SUSTAINED RELEASE TABLETS IN HEALTHY VOLUNTEERS

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#### Abstract:

AIM: To compare the pharmacokinetics and bioavailability of ketoprofen sustained release tablets (ST) with those of regular tablets (Reference tablet, RT) in 10 healthy volunteers after single and repeated oral administrations in randomized crossover design. METHODS: A sensitive and rapid HPLC method was used to determine the serum ketoprofen concentration. RESULTS: The results from single oral dose in 8 healthy volunteers indicated that the C<sub>max</sub> of RT was significantly higher than that of ST. The T<sub>max</sub> and t<sub>1/2ke</sub> of ST were significantly longer than those of RT (P<0.01). The relative bioavailability of ST was found to be 97.13%. As there was no difference in the AUC between the two preparations, it can be concluded that the new sustained release tablet was bioequivalent to RT. The C<sub>min</sub> of ST and RT at steady state were 0.401μg·mL<sup>-1</sup> and 0.190 μg·mL<sup>-1</sup>, respectively, with a significant difference (P<0.01) between them. The ketoprofen concentration peak trough ratio (PTR) and the degree of fluctuation (DF) of ST were significantly smaller than those of RT. CONCLUSION: The new sustained release tablet showed less fluctuation of peak and trough serum drug concentrations than those of the regular tablet at steady state and exhibited good sustained release property.

Keywords: HPLC pharmacokinetics bioavailability ketoprofen

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