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论文

布洛芬片剂生物利用度的研究

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摘要:

本文试制出新处方布洛芬片剂,选择山东新华制药厂三种片剂:市售处方A、新处方片剂B和C,以及英国Boots公司的片剂D,进行体外溶出速率和人体生物利用度试验,并测定了生产A,B(和C),D片剂的布洛芬原料A′,B′,D′的粒度,比较了A′,D′的晶型。实验表明,国内外原料晶型相同,A′,B′,D′平均粒径分别为130.0,36.6,56.6μm。A与D生物不等效,B和C与D生物等效。提高国产片剂生物利用度的因素主要与原料粒度、处方组成和制备工艺有关。

关键词: 布洛芬片剂 生物利用度 生物等效性 体内外相关性

STUDIES ON THE BIOAVAILABILITY OF IBUPROFEN TABLETS

LUAN Li-Biao; MAO Feng-Fei and TU Xi-De

Abstract:

New formulations were developed to increase the relative bioavailability of ibuprofen tablets produced by Shan Dong Xin Hua Pharmaceutical Factory in China. The dissolution rates of the tablets available in the Chinese market(A), the tablets of the new formulations (B and C) and the reference tablets made by British Boots Company (D) were determined. Human bioavailability studies were conducted to assess the *in vivo* performances of A, B and C relative to D by GC. The particle sizes of ibuprofen raw materials (A′, B′, D′) used for producing tablets (A, B and C, D) were ascertained and the differences of crystal forms between A′ and D′ were compared.The crystal forms of A′ and D′ were found to be the same, with no phenomena of polymorphism occurring, The mean surface area diameters of A′, B′ and D′ were 130.0, 36.6 and 56.6 μm respectively. Mean dissolution time (MDT) *in vitro* for A, B, C and D was 21.95, 5,322, 12.41 and 12.37 min respectively, *In vivo*, formulation A was bioinequivalent to D. The new formulation B was bioequivalent to D from the extent of absorption, while B was superior to D in the rate of absorption. The new formulation C exhibited an absorption effectiveness higher than D. Moreover, the percent of ibuprofen absorbed at time t after drug administration was correlated with the dose dissolved in *in vitro* test at time t/5 ($p<0.01$). The higher relative bioavailability of B and C over A was related to particle size of ibuprofen material, formulation and technological process.

Keywords: Bioavailability Bioequivalence Correlation *in vitro/in vivo* Ibuprofen tablet

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