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贝诺酯片剂的研制及生物利用度研究

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摘要:

通过减小药物粒径,提高贝诺酯片剂的生物利用度。在市售片以A(500mg)基础上研制了新处方片剂B(400mg)。建 立贝诺酯片剂体外溶出度试验方法,即以表面活性剂溶液作溶出介质,以浆法进行溶出度测定。用HPLC法测定贝诺酯 在体内的水解产物水杨酸和扑热息痛的血药浓度。结果表明药物研磨粉碎前后体外溶出速度常数分别为

0.0152min-1及0.0337min<sup>-1</sup>(P<0.001)。A及B体外平均溶出时间分别为42.25min及15.77min(P<0.001)。体内 研究表明A及B水杨酸的Cmax,Tn,AUC之间均无显著性差异(P>0.1)(A,B的服用量分别为4.5g及3.6g),B的相对生物 利用度为125.59%。

关键词: 贝诺酯 水扬酸 扑热息痛 表面活性剂 生物利用度

### STUDIES ON FORMULATION AND BIOAVAILABILITY OF BENORILATE TABLETS

J Chen and XD Tu

#### Abstract:

A new new formulation tablet B was developed and compared with tablet A with thepurpose of improving the bioavailability of benorilate by rebucing its particle size, The dissolution ratein uitro was determined by paddle method and using surfactant solution medlum, The plasma concentra-tions of hydrulyzates which are salicylic acid and paracetamol from benorilate in vivo were measuted byHPLC. The dissolution ▶陈俊 rates of ground and unground drug are 0.0337 min-1 and 0.0152 min-1 (P< 0.001) respectively. Compared with tablet A, the cumulative dissolution percentage of B ishigher. The mean dissolution time of B and A are I5. 77 min and 42.25 min(P<0. 001)respec-tively-The study in uiuo showed that the Cmax, Tp and AUC of salicylic acid for these two formulationshave no significant difference (P>0.1), The relative bioavailability of B to A is I25.59%. Their invivo process fits one-compartment medel and first order elimination.

Keywords: Salicylic acid Paracetamol Surfactant Bioavailability Benorilate

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1. 晁若冰; 陈涛; 丁世致. RP-HPLC法测定贝诺酯及其有关物质[J]. 药学学报, 1999, 34(10): 782-785

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