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论文

氯雷他定血药浓度的HPLC荧光检测法及生物等效性研究

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摘要：

目的建立高效液相色谱法荧光检测血浆中氯雷他定(loratadine)含量的方法,以评价氯雷他定的相对生物利用度。方法色谱柱为Alltech C_{18},4.6 mm×150 mm;流动相为乙腈-水-冰醋酸-三乙胺(90∶100∶6∶0.15);流速为1 mL·min^{-1};荧光检测器测定波长,E_x＝274 nm,E_m＝450 nm。结果HPLC测定线性范围为0.2～30 μg·L^{-1},最低定量限0.2 μg·L^{-1},方法回收率为96%～98%。人体生物利用度结果表明,实验片、胶囊与对照片间的AUC,t_{max},C_{max}和$t_{1/2}$β均无显著性差异(P>0.05),两者的相对生物利用度分别为107%±17%和100%±14%。AUC和C_{max}经可信区间法检验生物等效。结论3种制剂生物等效。

关键词： 氯雷他定 生物利用度 荧光检测 HPLC

Determination of loratadine in human plasma by HPLC with fluorescence detector and study on its bioavailability

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Abstract:

AimTo establish an HPLC-fluorescence method for determination of loratadine in human plasma and evaluate its relative bioavailability. MethodsAn Alltech-C_{18} column and a mobile phase of acetonitrile-water-glacial acetic acid-triethylamine (90∶100∶6∶0.15) were used. The fluorescence detector was set at E_x 274 nm, E_m 450 nm. The flow rate was 1 mL·min^{-1}. ResultsThe calibration curve was linear over a concentration range of 0.2-30 μg·L^{-1}. The limit of quantification was 0.2 μg·L^{-1}. The average method recoveries varied from 96% to 98%. The results showed AUC, t_{max}, C_{max} and $t_{1/2}$β between the testing tablets, testing capsules and reference tablets had no significant difference (P>0.05). Relative bioavailabilities were 107%±17% and 100%±14% respectively. ConclusionThe three formulations were bioequivalent.

Keywords: bioavailability fluorescence detection HPLC loratadine

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