药学学报 2003, 38(6) 455-457 DOI: ISSN: CN:

论文

人血浆中非那雄胺的HPLC-MS法测定

李向阳;丁黎;李丽敏;郝歆愚;张正行

1.青海医学院 药理教研室, 青海 西宁 810001； 2. 中国药科大学 药物分析教研室, 江苏 南京 210009；3. 南京医科大学 药理教研室, 江苏 南京 210008

摘要：

目的建立人血浆中非那雄胺的HPLC-MS测定法,以测定志愿者口服非那雄胺片剂后的血药浓度,并对供试制剂和参比制剂的生物等效性进行评价。方法血样经0.1 mol·L^{-1}NaOH碱化后用重蒸乙酸乙酯提取,进行HPLC-MS分析,色谱柱为Hypersil ODS （5 μm,250 mm×4.6 mm）,流动相为甲醇-水 (85∶15),内标为甲地孕酮,检测离子为*m/z* 395（非那雄胺）、*m/z* 407(内标),裂解电压为120 V。20名健康志愿者交叉口服供试片和参比片,计算主要药代动力学参数及相对生物利用度,以判断生物等效性。在1～200 μg·L^{-1}非那雄胺与内标峰面积比值与浓度线性关系良好（*R*=0.998 6）, 检测限为0.05 μg·L^{-1},回收率为85.9%～98.7%。以AUC_{0-24}计算的非那雄胺片剂的相对生物利用度为(100±13)%。结论建立的分析方法灵敏、准确、简便。统计学结果表明两种制剂生物等效。

关键词： 非那雄胺 HPLC-MS 生物等效性 血浆

Determination of finasteride in human plasma by HPLC-MS

LI Xiang-yang; DING Li; LI Li-min; HAO Xin-yu; ZHANG Zheng-xing

Abstract:

AimTo develop an HPLC-MS assay for determination of finasteride in human plasma and to investigate the bioequivalence in healthy volunteers. MethodsAfter alkalization with sodium hydroxide, plasma was extracted with ethyl acetate and separated using a C_{18} column with a mobile phase of methanol-water (85∶15). LC-ESI-MS was performed in the selected ion monitoring (SIM) mode using target ions at *m/z* 395 for finasteride and *m/z* 407 for the IS. The fragmentor voltage was 120 V. A randomized crossover design was performed in 20 healthy volunteers. In the two study periods, a single 10 mg dose of each tablet was administered to each volunteer. ResultsCalibration curves were linear over the range 1-200 μg·L^{-1} (*R*=0.998 6). The limit of determination for finasteride in plasma was 0.05 μg·L^{-1}. The recovery of finasteride from plasma was in the range of 85.9%-98.7%. The results of variance analysis and two one-side *T*-test showed that there was no significant difference between the two formulations in the AUC and C_{max}. Conclusion The assay was proved to be sensitive, accurate and convenient. The two formulations were bioequivalent.

Keywords: HPLC-MS bioequivalence plasma finasteride

收稿日期 2002-08-24 修回日期 网络版发布日期

DOI:

基金项目:

通讯作者: 李向阳

作者简介:

参考文献：

本刊中的类似文章

文章评论 (请注意:本站实行文责自负, 请不要发表与学术无关的内容!评论内容不代表本站观点.)

反馈人		邮箱地址	
反馈标题		验证码	1574