

技术交流

LC-MS/MS法测定人全血中环孢素A浓度及环孢素眼用乳剂健康人体药代动力学研究

王淑民¹; 李鹏飞²; 赵秀丽¹; 马萍²; 刘丽宏²

1. 首都医科大学附属北京同仁医院, 北京100730 2. 第二炮兵总医院药剂科, 北京100088

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摘要 建立液相色谱-质谱联用法测定人全血中环孢素A浓度, 选用Kromasil-C₁₈色谱柱(20 mm×4.6 mm×5 μm), 以甲醇1 mmol·L⁻¹甲酸铵溶液为流动相, 采用梯度洗脱进行分离, 样品用沉淀蛋白法处理后进样, 流速1.1 mL·min⁻¹, 柱温60 °C, 进样量20 μL。选用3200 QTrap型三重四极杆串联质谱仪的多重反应监测(MRM)扫描方式进行检测。环孢素A的线性范围为0.2~20.00 μg·L⁻¹, 定量下限为0.2 μg·L⁻¹。准确度与精密度结果显示, 方法日间、日内变异均小于15%, 相对偏差为-12.60%~12.80%, 方法提取回收率为(98.1±4.7)%, 稳定性较好。所建立的方法快速、灵敏、专属性强、重现性好, 可用于环孢素眼用乳剂健康人体药代动力学研究。

关键词 [液相色谱-质谱联用法](#) [环孢素A](#) [药代动力学](#)

分类号

LC-MS/MS Determination of Cyclosporin in Human Blood and Application in Pharmacokinetics

WANG Shu-min¹; LI Peng-fei²; ZHAO Xiu-li¹; MA Ping²; LIU Li-hong²

1. Beijing Tongren Hospital, Capital University of Medical Science, Beijing 100730, China; 2. Pharmacy Department of the Second Artillery General Hospital, Beijing 100088, China

Abstract The Cyclosporin in human blood was determined by LC-MS/MS. Cyclosporin and the internal standard were extracted from blood by methanol, which was used as deproteinated solvent, and then separated on a Kromasil-C₁₈ column (20 mm×4.6 mm×5 μm). The mobile phase was consisted of methanol 1 mmol·L⁻¹ ammonium formate maintained at 60 °C. The flow rate was 1.1 mL·min⁻¹, and 20 μL aliquot of residues were injected into the LC-MS/MS system. Detection was carried out by multiple reaction monitoring on 3200 Qtrap LC-MS/MS system. The assay is linear over the range of 0.20—20.00 μg·L⁻¹ with a lower limit of quantitation of 0.20 μg·L⁻¹. Intra- and inter-day precision are less than 15%. The relative deviation is in the range of -12.60%—12.80%. The recovery of Cyclosporin is (98.1±4.7)%, and stability is good. It is a rapid, sensitive, selective and reliable method for the determination of Cyclosporin in human blood. The assay can be applied for the determination of Cyclosporin in human blood and the study on pharmacokinetics.

Key words [LC-MS/MS](#) [Cyclosporin](#) [pharmacokinetics](#)

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