



冯淑玲, 庄波阳, 王凌. HPLC测定盐酸苯海拉明注射液中二苯甲醇和二苯甲酮含量[J]. 中国现代应用药学, 2013, 30(5):519-522

HPLC测定盐酸苯海拉明注射液中二苯甲醇和二苯甲酮含量

Determination of Diphenylmethanol and Diphenylmethanone in Diphenhydramine Hydrochloride Injection by HPLC

投稿时间: 2012-06-19 最后修改时间: 2012-11-11

DOI:

中文关键词: [盐酸苯海拉明注射液](#) [高效液相色谱法](#) [有关物质](#) [二苯甲醇](#) [二苯甲酮](#)

英文关键词: [diphenhydramine hydrochloride injection](#) [HPLC](#) [related substances](#) [diphenylmethanol](#) [diphenylmethanone](#)

基金项目:

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中文摘要:

目的 采用高效液相色谱法建立同时测定盐酸苯海拉明注射液中二苯甲醇和二苯甲酮的方法。方法 色谱柱Agilent氰基柱(4.6 mm×250 mm, 5 μm)流动相为乙腈-20 mmol·L⁻¹乙酸铵(用甲酸调pH值至6.5)(50:50), 检测波长为255 nm。结果 二苯甲醇浓度在1.0~53.10 μg·mL⁻¹内与峰面积呈良好的线性关系, r为1.000; 二苯甲酮浓度在0.021 22~53.05 μg·mL⁻¹内与峰面积呈良好的线性关系, r为1.000; 二苯甲醇加样回收率的平均值为99.8%, RSD=0.8%; 二苯甲酮加样回收率的平均值为100.4%, RSD=1.3%。结论 本方法简便、准确可靠, 适用于盐酸苯海拉明注射液中二苯甲醇和二苯甲酮两个主要有关物质的控制。

英文摘要:

OBJECTIVE To establish an HPLC method for determining the contents of diphenylmethanol and diphenylmethanone in diphenhydramine hydrochloride injection. METHODS The condition of detection were: Agilent CN column (4.6 mm×250 mm), the mobile phase consisted of acetonitrile and 20 mmol·L⁻¹ ammonium acetate (adjust with formic acid to pH 6.5)(50:50), the UV detection wavelength was 255 nm. RESULTS The calibration curves were linear in the range of 0.53.10 μg·mL⁻¹ for diphenylmethanol (r=1.000); the calibration curves were linear in the range of 0.021 22~53.05 μg·mL⁻¹ for diphenylmethanone (r=1.000). The average recovery of diphenylmethanol was 99.8%(RSD=0.8%); the average recovery of diphenylmethanone was 100.4%(RSD=1.3%). CONCLUSION The method is simple, accurate, reliable and can be used for the quality control of diphenylmethanol and diphenylmethanone in diphenhydramine hydrochloride injection.

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