



### 毛细管气相色谱法测定2-[2-甲基-4-[4-[2-嘧啶基]甲硫基]苯氧基]乙酸中有机溶剂残留量

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**摘要** 目的 建立2-[2-甲基-4-[4-[2-嘧啶基]甲硫基]苯氧基]乙酸原料药中乙腈、1, 4-二氧六环、四氢呋喃、乙酸乙酯、丙酮、乙醇和异丙醇7种有机溶剂残留量的气相色谱测定方法。方法 采用DB-1 (30 m×0.53 mm, 5.00 μm) 毛细管色谱柱, 氢火焰离子化检测器(FID), 以氮气为载气, 进样口温度160 ℃, 检测器温度为250 ℃, 柱温为程序升温; 分流进样, 外标法计算残留溶剂的含量。结果 7种有机溶剂均得到有效分离, 在考察的浓度范围内, 回收率及线性关系良好, 且3批样品中有机溶剂残留量均符合规定。结论 本方法操作简便, 精密度好, 准确可靠, 适用于该原料中7种残留有机溶剂的同时测定。

**关键词:** 毛细管气相色谱法 2-[2-甲基-4-[4-[2-嘧啶基]甲硫基]苯氧基]乙酸 有机溶剂残留量

**Abstract:** OBJECTIVE To establish a capillary GC method for the determination of residual solvents including ethanol, acetonitrile, acetone, isopropanol, ethyl acetate, dioxane and THF in 2-[2-methyl-4-[[2-pyrimidin-4-yl] methylsulfanyl]phenoxy]acetic acid. METHODS The residual organic solvents were separated on DB-1 capillary column (30 m×0.53 mm, 5.00 μm). FID was used as detector with a temperature of 250 ℃, and the inlet temperature was 160 ℃. The carrier gas was nitrogen, and the column temperature was programmed set. The contents of residual solvents were calculated by external standard method. RESULTS The seven residual organic solvents were completely separated, the recovery rates and linear relationship were good, and three batches of samples all met the requirements. CONCLUSION The method is simple, accurate, and reproducible, so it can be used for the detection of seven residual organic solvents in the raw.

**Keywords:** GC, 2-[2-methyl-4-[[2-pyrimidin-4-yl] methylsulfanyl]phenoxy]acetic acid, residual solvent

收稿日期: 2013-01-18;

基金资助:

国家“重大新药创制”药物分子设计高效筛选平台(2012ZX09103003-001-002)

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引用本文:

车慧\*, 靳守东, 郑志兵等. 毛细管气相色谱法测定2-[2-甲基-4-[4-[2-嘧啶基]甲硫基]苯氧基]乙酸中有机溶剂残留量[J]. 中国药学期刊. 2013.V48(7): 562-564

CHE Hui-\*, JIN Shou-Dong-, ZHENG Zhi-Bing- etc .Determination of Residual Organic Solvents in 2-[2-Methyl-4-[[2-pyrimidin-4-yl] methylsulfanyl] phenoxy] acetic Acid by Capillary Gas Chromatography[J] Chinese Pharmaceutical Journal, 2013,V48(7): 562-564

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