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HPLC测定硫唑嘌呤片有关物质

HPLC Determination of the Related Substances in Azathioprine Tablets

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中文摘要:

目的 采用高效液相色谱法测定硫唑嘌呤片有关物质。方法 采用十八烷基硅烷键合硅胶色谱柱(200 mm×4.6 mm, 5 μm), 以醇-0.05%醋酸钠溶液(18:82)为流动相, 流速为1.2 mL·min⁻¹, 检测波长为300 nm。结果 硫唑嘌呤片中的2个典型杂质6-巯基嘌呤氯-1-甲基-4-硝基咪唑的线性范围均为0.125~1.80 μg·mL⁻¹(r分别为0.999 7和0.999 9), 检出限分别为0.787 ng和0.933 ng, 平均收率为100.3%(RSD=0.64%)和100.0%(RSD=0.14%)。结论 高效液相色谱法测定硫唑嘌呤片有关物质简便、快速, 测定结果准确、可靠

英文摘要:

OBJECTIVE To establish an HPLC method for determination of related substances in Azathioprine Tablets. METHOD The C₁₈ column (200 mm×4.6 mm, 5 μm) was used. The mobile phase consisted of methanol and 0.05% of sodium acetate solution(18:82) at the flow rate of 1.2 mL·min⁻¹, and the detection wavelength was set at 300 nm. RESULTS The linear ranges of the two typical related substances mercaptopurine and 5-chloro-1-methyl-4-nitroimidazole in Azathioprine Tablets were all 0.125-1.80 μg·mL⁻¹(r=0.9997 and 0.9999) with the detection limits of 0.787 ng and 0.933 ng, and average recoveries were 100.3% and 100.0% with the RSD of 0.64% and 0.14%. CONCLUSION The method proposed for determining the related substances of Azathioprine Tablets is simple, quick and the result is accurate and specific

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