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加校正因子的主成分自身对照法测定布洛芬中杂质4-异丁基苯甲酸的含量

Determine the Content of Impurity 4-isobutylbenzoic Acid in Ibuprofen with the Correction Factor

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中文摘要:

目的 建立一种加校正因子的自身对照法测定布洛芬中已知杂质(4-异丁基苯甲酸)的方法。方法 测定布洛芬和4-异丁基苯甲酸的线性方程,以斜率计算杂质4-异丁基苯甲酸相对于主成分布洛芬的校正因子;通过方法学考察,表明所采用的高效液相色谱法测定布洛芬中4-异丁基苯甲酸的含量可行;再采用外标法和加校正因子的主成分自身对照法分别测定三批布洛芬中4-异丁基苯甲酸的含量,并用统计学软件SPSS 13.0分析两组数据的差异。结果 测得4-异丁基苯甲酸的校正因子为0.129,经方法学考察表明此方法准确可靠,且应用统计学软件分析本方法与外标法测得数据,结果表明两方法所测得数据无统计学差异。结论 用加校正因子的主成分自身对照法测定布洛芬中4-异丁基苯甲酸的含量,方法准确可行。

英文摘要:

OBJECTIVE The self contrast and correction factor method was established to measure the content of 4-isobutylbenzoic acid in ibuprofen. METHODS Prepare series of solutions containing 4-isobutylbenzoic acid and ibuprofen for determining the correction factor. Inject the solutions into two different equipments and record the chromatogram. Measure the peak area of 4-isobutylbenzoic acid and ibuprofen and calculate the correction factor. Use the slopes of linear equations to determine the correction factor between 4-isobutylbenzoic acid and ibuprofen. Then, validate the analytical method to ensure that HPLC method for the determination of impurity 4-isobutylbenzoic acid in ibuprofen meets the requirement for the intended analytical applications. At last, compare the results determined by the external standard method and the self contrast and correction factor method with statistical software SPSS13.0. RESULTS The correction factor between 4-isobutylbenzoic acid and ibuprofen is 0.129, and there is no statistical difference between the contents of impurity 4-isobutylbenzoic acid in ibuprofen determined by the two methods. CONCLUSION The self contrast and correction factor was found to be accurate, linear, sensitive and stable.

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