医薬品医療機器レギュラトリーサイエンス
Pharmaceutical and Medical Device Regulatory Science
Vol. 47, No. 3, 210～218 (2016)

報告書

平成25年度「日本薬局方の試験法等に関する研究」研究報告[*3]
金属不純物の分析法に関する研究

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Analytical Method for the Evaluation of Elemental Impurities in Pharmaceuticals Products

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Summary

Elemental impurity levels in pharmaceutical products are going to be controlled based on permitted daily exposures (PDEs) in drug products following the ICH (International Conference Harmonization) Q3D guideline. The purpose of this paper is to present a method to measure the elemental impurity concentrations in the final products by means of inductively coupled plasma mass spectrometry (ICPMS) using closed vessel digestion. As samples, a tablet and a large-volume injection were used and 7 elemental impurities of Class 1 (Cd, Pb, As, Hg) and Class 2A (Co, V, Ni) were analyzed. During sample preparation from tablets, fluoroboric acid was added to enhance oxidative degradation.

The products examined contained relatively low levels of elemental impurities, and good recoveries were obtained from both tablet and large-volume injection.

Key words

ICH Q3D, Elemental impurities, ICPMS