財団 Information ▶報告書

令和３年度「日本薬局方の試験法等に関する研究」研究報告
蛍光Ｘ線分析法を用いたICH-Q3Dに基づく日本薬局方医薬品の元素不純物管理に関する研究
EDXRFによるICH-Q3D元素不純物分析（第１報）*3

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Study on Quantitative Analysis of Elemental Impurities in Japanese Pharmacopoeia Pharmaceuticals Using X-Ray Fluorescence Analysis
ICH-Q3D Elemental Impurity Analysis by EDXRF I*3

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Summary

X-Ray fluorescence analysis was performed as a test method for determining elemental impurities in commercial levofloxacin 0.5 hydrate reagent (purity of 98.0 w/w% or higher) and Japanese Pharmacopoeia (JP) levofloxacin (LVFX) tablets according to the ICH-Q3D Guideline. Validation tests were conducted for (1) detection sensitivity, (2) specificity, and (3) accuracy, based on the procedures in the USP <735> X-Ray Fluorescence Spectrometry and the limit test for elemental impurities in the Japanese Pharmacopoeia 18: 2.66.

The results showed that all samples met the required criteria and indicate that X-ray fluorescence analysis is applicable to the analysis of elemental impurities as required by ICH-Q3D. In this evaluation, quantitative analysis of the samples was carried out by the fundamental parameter method (FP method) without the need for added internal standards.

Key words

X-Ray fluorescence spectrometry, EDXRF, Energy dispersive X-ray analyzer, Elemental impurities analysis, ICH-Q3D