財団 Information ▶報告書

令和４年度「日本薬局方の試験法等に関する研究」研究報告

EDXRFによるICH-Q3D元素不純物分析（第２報）*3
―米国薬局方USP＜735＞及び欧州薬局方EP 2.2.37の比較と考察―

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ICH-Q3D Elemental Impurity Analysis by EDXRF（Ⅱ）*3
―Comparison and Discussion of the United States Pharmacopeia USP <735> and the European Pharmacopoeia EP 2.2.37―

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Summary

The United States Pharmacopeia (USP) and European Pharmacopoeia (EP) general test methods include <735> X-RAY FLUORESCENCE SPECTROMETRY[1] and 2.2.37 X-RAY FLUORESCENCE SPECTROMETRY[2] as X-ray fluorescence analysis methods. However, the Japanese Pharmacopoeia does not list X-ray fluorescence analysis. Therefore, we performed elemental impurity analysis of ICH-Q3D[3] using an energy-dispersive X-ray fluorescence spectrometer and a limit test method while comparing USP and EP. The samples used were commercially available oral drugs, Irsogladine Maleate Tablets and Famotidine Tablets. Class 1：Arsenic (As), Mercury (Hg), Lead (Pb), Cadmium (Cd), Class 2A：Vanadium (V), Cobalt (Co), Nickel (Ni), and Class 2B：Palladium (Pd) elements were evaluated. All samples met the compliance criteria, indicating that X-ray fluorescence analysis can be applied to the analysis of elemental impurities in ICH-Q3D. In this context, further improvements in the sensitivity of X-ray fluorescence spectrometers are expected in the future.

Key words

X-Ray fluorescence spectrometry, EDXRF, Energy dispersive X-ray analyzer, Qualitative quantitative analysis, Quantitative analysis, Elemental impurities analysis, United States Pharmacopoeia, ICH-Q3D, European Pharmacopoeia