

令和5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3報）*³
—ICH-Q3Dに基づく日本薬局方医薬品の元素不純物管理の効率
化を目指した蛍光X線分析法を用いた元素不純物スクリー
ニング手法の標準化に関する研究—

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ICH-Q3D Elemental Impurity Analysis by EDXRF (Ⅲ)*³
—Study on Standardization of Elemental Impurity Screening Method Using X-ray
Fluorescence Spectrometry to Improve the Efficiency of Elemental Impurity
Control of Pharmaceuticals Listed in the Japanese Pharmacopoeia Based on
ICH Q3D—

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Summary

X-Ray fluorescence analysis was evaluated as a test method for ICH-Q3D elemental impurities using commercial titanium oxide reagent of various grades as a model for the analysis of inorganic additives. We also clarified the approximate relationship between the main component elements and sensitivity. We present an efficient standardized work flow for determining elemental impurities.

Key words

X-Ray fluorescence spectrometry, EDXRF, Energy dispersive X-ray analyzer, Qualitative quantitative analysis, Quantitative analysis, Titanium oxide, Elemental impurities analysis, ICH-Q3D