

[View on rigaku.com](http://www.rigaku.com)

PHARM024: Analysis of Trace Impurities in Pharmaceuticals

Introduction

The Impurity Guidelines for Pharmaceuticals (ICH-Q3D) set a permitted daily exposure (PDE) for impurity elements in oral preparations. ICP-OES and ICP-MS are used for the analysis of elemental impurities, but in recent years, XRF has been attracting increasing interest due to its simplicity in sample processing. Polarized optical energy dispersive X-ray fluorescence spectrometers have superior peak-to-background ratios for measurement spectra compared to conventional systems, enabling analysis with higher sensitivity.

Elemental analysis

Analysis:	Drug substance, additive, formulation
Use:	Manufacturing (Production)
Analyzed materials:	Cellulose
Analysis method:	Calibration method

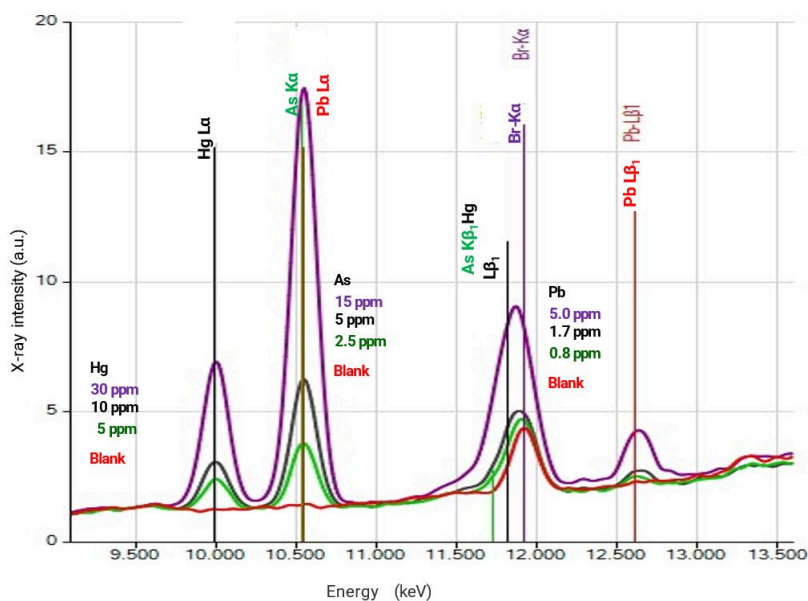


Figure 1: Qualitative spectra of mercury, lead, and arsenic

Table 1: NEX CG II detection limits and permitted daily exposure (PDE) for elemental impurities

Element	Class	PDE value μg	Concentration limit based on PDE and daily dose			NEX CG II Lower limit of detection $\mu\text{g/g(ppm)}$
			10g or less $\mu\text{g/g}$ (ppm)	5g $\mu\text{g/g}$ (ppm)	1g $\mu\text{g/g}$ (ppm)	
Cd	1	5	0.5	1	5	0.40
Pb	1	5	0.5	1	5	0.08
As	1	15	1.5	3	15	0.06
Hg	1	30	3	6	30	0.10
Co	2A	50	5	10	50	0.12
V	2A	100	10	20	100	0.12
Ni	2A	200	20	40	200	0.26

Conclusion

Clear X-ray fluorescence peaks were obtained from the measurement spectra of cellulose powder samples containing mercury (Hg), lead (Pb), and arsenic (As) in the ppm order. NEX CG II uses polarized optics to achieve a very low detection limit. The sensitivity of this analyzer allows for the analysis of seven trace elements of Class 1 and Class 2A, which are required to be tested under the impurity guidelines for pharmaceutical products.

Related products



NEX CG II Series

High-performance *indirect excitation* EDXRF for complex applications with trace elements and variable base matrices