

CERTIFIED
REFERENCE
MATERIALS



INORGANIC

SPEX CertiPrep is the industry leader for over 60 years in the CRM marketplace meeting the needs of laboratories worldwide with innovation and research.



Accredited by A2LA for ISO 17025 and Guide 34, and Certified by UL-DQS for ISO 9001.

USP <232> AND USP <233> ELEMENTAL IMPURITIES

In the pharmaceutical industry, the guidelines set by the United States Pharmacopeia (USP) and the International Conference on Harmonization (ICH) have pushed the pharmaceutical and nutraceutical industries to provide accurate, quantifiable results for the metal analysis in drugs, pharmaceutical substances and raw materials.

USP <232> outlines new limits and USP <233> outlines procedures in pharmaceutical products for Arsenic, Cadmium, Lead and Mercury. The proposed procedures focus on the use of ICP/MS (Inductively Coupled Plasma/Mass Spectrometry) for the analysis of low level impurities. ICP/MS instrumentation along with accurate ICP/MS standards allow for increased efficiency and accuracy of the analysis necessary to comply with the new regulations. In addition to the changes enacted by the USP, the ICH is also planning to release similar guidelines on elemental impurities in pharmaceutical materials and products.

Developed in accordance with USP <232> Elemental Impurities and USP <233> Procedures, SPEX CertiPrep is proud to offer these additions to our Consumer Safety Compliance Standards line. These standards can be used as a calibration or check standard to verify Oral Daily Dose PDE, Parenteral Component Limit or Parenteral Daily Dose PDE. Our extensive experience in creating quality trace metal standards coupled with your ICP/MS analysis will ensure your company will remain compliant with the new and changing regulations.

■ UL and A2LA Stamp of Approval

- Our Quality System is Certified by UL-DQS to ISO 9001:2008
- Accredited by A2LA for ISO 17025:2005 and ISO Guide 34-2009

■ Inorganic CRMs for:

- AA (Atomic Absorption)
- GFAA (Graphite Furnace Atomic Absorption)
- ICP (Inductively Coupled Plasma)
- ICP/MS (Inductively Coupled Plasma - Mass Spectrometry)
- IC (Ion Chromatography)
- XRF (X-Ray Fluorescence)
- Classical Wet Chemistry Techniques
- All analytical techniques which require precise analytical reference materials are required

■ Features of SPEX CertiPrep Inorganic Reference Materials:

- Single element standards are offered in 1,000 mg/L and 10,000 mg/L concentrations
- Standards packaged in a variety of convenient sizes, including 125mL, 250mL, and 500mL bottles
- Wide selection of stock multi-component standards available
- Accuracy and stability of components are guaranteed
- Custom packaging available
- Custom blends manufactured upon request



■ Value of SPEX CertiPrep Inorganic Reference Materials:

- All standards and starting materials are triple checked for quality
- All standards are directly traceable to NIST SRMs, where available
- Trace impurities are quantified by ICP/MS to ppb levels and reported in our SPEXertificate
- Up to 68 elemental impurities reported on our Inorganic Certificate of Analysis.
- Weights used are traceable to NIST



SPEX CertiPrep

Inorganic & Organic Certified Reference Materials

 **Fisher
Scientific**

USP-TXM2 (125 mL)	
USP Oral Elemental Impurities A	
Cadmium	25 mg/kg
Mercury	15 mg/kg
Lead	5 mg/kg
Arsenic	1.5 mg/kg

USP-TXM5 (125 mL)	
USP Oral/Parenteral Elemental Impurities C	
Copper	1000 mg/kg
Nickel	500 mg/kg
Molybdenum	100 mg/kg
Vanadium	100 mg/kg

USP-TXM3 (125 mL)	
USP Precious Metal Impurities B (with Os)	
Iridium	100 mg/kg
Osmium	100 mg/kg
Palladium	100 mg/kg
Platinum	100 mg/kg
Rhodium	100 mg/kg
Ruthenium	100 mg/kg

USP-TXM4 (125 mL)	
USP Precious Metals Impurities B (without Os)	
Iridium	100 mg/kg
Palladium	100 mg/kg
Platinum	100 mg/kg
Rhodium	100 mg/kg
Ruthenium	100 mg/kg

Can't find the standard you're looking for?

SPEX CertiPrep can custom make any standard in any combination.

Call your local sales representative for more information.



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