



USP <232>, <233> & <2232> Elemental Impurities

Analytical Standards for USP <232> & <233> Elemental Impurities

The new 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 metal analysis in drugs, pharmaceutical substances and raw materials.

USP <232> outlines new limits 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, 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.

For additional product information, please visit www.spexcertiprep.com/products/USP.

Oral Elemental Impurities A				
Element	Concentration	Volume	Matrix	Part #
Cadmium	5 mg/kg	125 mL	5% HNO ₃ /1% HCl	USP-TXM2A
Mercury	30 mg/kg			
Lead	5 mg/kg			
Arsenic	15 mg/kg			

Precious Metal Impurities B (with Os)				
Element	Concentration	Volume	Matrix	Part #
Iridium	100 mg/kg	125 mL	15% HCl	USP-TXM3
Osmium	100 mg/kg			
Palladium	100 mg/kg			
Platinum	100 mg/kg			
Rhodium	100 mg/kg			
Ruthenium	100 mg/kg			

CERTIFIED REFERENCE MATERIALS

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 to ISO/IEC 17025:2005 & ISO Guide 34:2009. Certified by UL-DQS, ISO 9001:2008.

USP <232>, <233> & <2232> Elemental Impurities (cont'd)

Precious Metal Impurities B (without Os)				
Element	Concentration	Volume	Matrix	Part #
Iridium	100 mg/kg	125 mL	15% HCl	USP-TXM4
Palladium	100 mg/kg			
Platinum	100 mg/kg			
Rhodium	100 mg/kg			
Ruthenium	100 mg/kg			

Oral Elemental Impurities C				
Element	Concentration	Volume	Matrix	Part #
Copper	3,000 mg/kg	125 mL	5% HNO ₃	USP-TXM5A
Nickel	200 mg/kg			
Molybdenum	3,000 mg/kg			
Vanadium	100 mg/kg			
Chromium	11,000 mg/kg			

Parenteral Elemental Impurities C				
Element	Concentration	Volume	Matrix	Part #
Copper	300 mg/kg	125 mL	5% HNO ₃	USP-TXM5B
Nickel	20 mg/kg			
Molybdenum	1,500 mg/kg			
Vanadium	10 mg/kg			
Chromium	1,100 mg/kg			

Parenteral Elemental Impurities D				
Element	Concentration	Volume	Matrix	Part #
Lead	5 mg/kg	125 mL	5% HNO ₃ /1% HCL	USP-TXM6A
Cadmium	2 mg/kg			
Arsenic	15 mg/kg			
Mercury	3 mg/kg			

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SPEX CertiPrep can make custom standards to meet your exact needs. Contact us for more information.



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