

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

- Oral, Parenteral, Inhalation, Precious Metal, and Elemental Impurities Mixes
- Procedures focused on the use of ICP-MS for analysis of low level impurities



Analytical Standards for USP <232>, <233> and <2232> 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 help ensure your company will remain compliant with the new and changing regulations.



Inorganic Certified Reference Materials



Designed for use with ICP-MS



Supplied with a Certificate of Analysis



ISO Accredited Standards

Analytical Standards for USP <232>, <233> and <2232> Elemental Impurities

USP 232 Revision 40, Oral 2A

Element	Concentration	Volume	Matrix	Catalog Number
Cobalt	50 mg/kg	125 mL	2% HNO ₃	USPORAL2A
Nickel	200 mg/kg			
Vanadium	100 mg/kg			

USP 232 Revision 40, Oral 2B Mix 1

Element	Concentration	Volume	Matrix	Catalog Number
Selenium	150 mg/kg	125 mL	2% HNO ₃	USPORAL2B1
Silver	150 mg/kg			
Thallium	8 mg/kg			

USP 232 Revision 40, Oral 2B Mix 2

Element	Concentration	Volume	Matrix	Catalog Number
Gold	100 mg/kg for each component	125 mL	15% HCl	USPORAL2B2
Iridium				
Osmium				
Palladium				
Platinum				
Rhodium				
Ruthenium				

USP 232 Revision 40, Oral 3 Mix 1

Element	Concentration	Volume	Matrix	Catalog Number
Barium	1,400 mg/kg	125 mL	10% HNO ₃	USPORAL31
Chromium	11,000 mg/kg			
Copper	3,000 mg/kg			
Lithium	550 mg/kg			

Analytical Standards for USP <232>, <233> and <2232> Elemental Impurities

USP 232 Revision 40, Oral 3 Mix 2

Element	Concentration	Volume	Matrix	Catalog Number
Antimony	1,200 mg/kg	125 mL	5% HNO ₃ /tr. Tartaric Acid/tr. HF	USPORAL32
Molybdenum	3,000 mg/kg			
Tin	6,000 mg/kg			

USP 232 Revision 40, Parenteral 2A

Element	Concentration	Volume	Matrix	Catalog Number
Cobalt	5 mg/kg	125 mL	2% HNO ₃	USPPARENT2A
Nickel	20 mg/kg			
Vanadium	10 mg/kg			

USP 232 Revision 40, Parenteral 2B Mix 1

Element	Concentration	Volume	Matrix	Catalog Number
Selenium	80 mg/kg	125 mL	2% HNO ₃	USPPARENT2B1
Silver	10 mg/kg			
Thallium	8 mg/kg			

USP 232 Revision 40, Parenteral 2B Mix 2

Element	Concentration	Volume	Matrix	Catalog Number
Gold	100 mg/kg	125 mL	10% HCL	USPPARENT2B2
Iridium	10 mg/kg			
Osmium	10 mg/kg			
Palladium	10 mg/kg			
Platinum	10 mg/kg			
Rhodium	10 mg/kg			
Ruthenium	10 mg/kg			

Analytical Standards for USP <232>, <233> and <2232> Elemental Impurities

USP 232 Revision 40, Parenteral 3

Element	Concentration	Volume	Matrix	Catalog Number
Antimony	90 mg/kg	125 mL	5% HNO ₃ /tr. Tartaric Acid/tr. HF	USPPARENT3
Barium	700 mg/kg			
Chromium	1,100 mg/kg			
Copper	300 mg/kg			
Lithium	250 mg/kg			
Molybdenum	1,500 mg/kg			
Tin	600 mg/kg			

USP 232 Revision 40, Inhalation Mix 1

Element	Concentration	Volume	Matrix	Catalog Number
Arsenic	2 mg/kg	125 mL	5% HNO ₃	USPINHL1
Cadmium	2 mg/kg			
Lead	5 mg/kg			
Mercury	1 mg/kg			

USP 232 Revision 40, Inhalation Mix 2A

Element	Concentration	Volume	Matrix	Catalog Number
Cobalt	3 mg/kg	125 mL	2% HNO ₃	USPINHL2A
Nickel	5 mg/kg			
Vanadium	1 mg/kg			

USP 232 Revision 40, Inhalation 2B, Mix 1

Element	Concentration	Volume	Matrix	Catalog Number
Selenium	130 mg/kg	125 mL	2% HNO ₃	USPINHL2B1
Silver	7 mg/kg			
Thallium	8 mg/kg			

Analytical Standards for USP <232>, <233> and <2232> Elemental Impurities

USP 232 Revision 40, Inhalation 2B, Mix 1

Element	Concentration	Volume	Matrix	Catalog Number
Gold	1 mg/kg for each component	125 mL	5% HCl	USPINHL2B2
Iridium				
Osmium				
Palladium				
Platinum				
Rhodium				
Ruthenium				

USP 232 Revision 40, Inhalation Mix 3

Element	Concentration	Volume	Matrix	Catalog Number
Antimony	20 mg/kg	125 mL	2% HNO ₃ /tr. Tartaric Acid/tr. HF	USPINHL3
Barium	300 mg/kg			
Chromium	3 mg/kg			
Copper	30 mg/kg			
Lithium	25 mg/kg			
Molybdenum	10 mg/kg			
Tin	60 mg/kg			

Oral Elemental Impurities A

Element	Concentration	Volume	Matrix	Catalog Number
Arsenic	1.5 mg/kg	125 mL	5% HNO ₃	USPTXM2
Cadmium	25 mg/kg			
Lead	5 mg/kg			
Mercury	15 mg/kg			

Analytical Standards for USP <232>, <233> and <2232> Elemental Impurities

Oral Elemental Impurities A				
Element	Concentration	Volume	Matrix	Catalog Number
Arsenic	15 mg/kg	125 mL	5% HNO ₃ /1% HCl	USPTXM2A
Cadmium	5 mg/kg			
Lead	5 mg/kg			
Mercury	30 mg/kg			

Precious Metal Impurities B (with Os)				
Element	Concentration	Volume	Matrix	Catalog Number
Iridium	100 mg/kg for each component	125 mL	15% HCl	USPTXM3
Osmium				
Palladium				
Platinum				
Rhodium				
Ruthenium				

Precious Metal Impurities B (without Os)				
Element	Concentration	Volume	Matrix	Catalog Number
Iridium	100 mg/kg for each component	125 mL	15% HCl	USPTXM4
Palladium				
Platinum				
Rhodium				
Ruthenium				

Analytical Standards for USP <232>, <233> and <2232> Elemental Impurities

Oral/Parenteral Elemental Impurities C				
Element	Concentration	Volume	Matrix	Catalog Number
Copper	1,000 mg/kg	125 mL	5% HNO ₃	USPTXM5
Molybdenum	100 mg/kg			
Nickel	500 mg/kg			
Vanadium	100 mg/kg			

Oral Elemental Impurities C				
Element	Concentration	Volume	Matrix	Catalog Number
Chromium	11,000 mg/kg	125 mL	5% HNO ₃	USPTXM5A
Copper	3,000 mg/kg			
Molybdenum	3,000 mg/kg			
Nickel	200 mg/kg			
Vanadium	100 mg/kg			

Parenteral Elemental Impurities C				
Element	Concentration	Volume	Matrix	Catalog Number
Chromium	1,100 mg/kg	125 mL	5% HNO ₃	USPTXM5B
Copper	300 mg/kg			
Molybdenum	1,500 mg/kg			
Nickel	20 mg/kg			
Vanadium	10 mg/kg			

Analytical Standards for USP <232>, <233> and <2232> Elemental Impurities

Parenteral Elemental Impurities D				
Element	Concentration	Volume	Matrix	Catalog Number
Arsenic	15 mg/kg	125 mL	5% HNO ₃ /1% HCl	USPTXM6A
Cadmium	2 mg/kg			
Lead	5 mg/kg			
Mercury	3 mg/kg			

Distributed by Fisher Scientific. Contact us today:

In the United States

Order online: fishersci.com

Call customer service: 1-800-766-7000

In Canada

Order online: fishersci.ca

Call customer service: 1-800-234-7437

