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Analytical Standards for 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.

USP 232 Revision 40, Oral 2A

Element	Concentration	Volume	Matrix	Part #
Cobalt	50 mg/kg	125 mL	2% HNO ₃	USP-ORAL2A
Nickel	200 mg/kg			
Vanadium	100 mg/kg			

USP 232 Revision 40, Oral 2B Mix 1

Element	Concentration	Volume	Matrix	Part #
Selenium	150 mg/kg	125 mL	2% HNO ₃	USP-ORAL2B-1
Silver	150 mg/kg			
Thallium	8 mg/kg			

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

USP 232 Revision 40, Oral 2B Mix 2

Element	Concentration	Volume	Matrix	Part #
Gold	100 mg/kg for each component	125 mL	15% HCl	USP-ORAL2B-2
Iridium				
Osmium				
Palladium				
Platinum				
Rhodium				
Ruthenium				

USP 232 Revision 40, Oral 3 Mix 1

Element	Concentration	Volume	Matrix	Part #
Barium	1,400 mg/kg	125 mL	10% HNO ₃	USP-ORAL3-1
Chromium	11,000 mg/kg			
Copper	3,000 mg/kg			
Lithium	550 mg/kg			

USP 232 Revision 40, Oral 3 Mix 2

Element	Concentration	Volume	Matrix	Part #
Antimony	1,200 mg/kg	125 mL	5% HNO ₃ /tr. Tartaric Acid/tr. HF	USP-ORAL3-2
Molybdenum	3,000 mg/kg			
Tin	6,000 mg/kg			

USP 232 Revision 40, Parenteral 2A

Element	Concentration	Volume	Matrix	Part #
Cobalt	5 mg/kg	125 mL	2% HNO ₃	USP-PARENT2A
Nickel	20 mg/kg			
Vanadium	10 mg/kg			

USP 232 Revision 40, Parenteral 2B Mix 1

Element	Concentration	Volume	Matrix	Part #
Selenium	80 mg/kg	125 mL	2% HNO ₃	USP-PARENT2B-1
Silver	10 mg/kg			
Thallium	8 mg/kg			

USP 232 Revision 40, Parenteral 2B Mix 2

Element	Concentration	Volume	Matrix	Part #
Gold	100 mg/kg	125 mL	10% HCl	USP-PARENT2B-2
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> & <2232> Elemental Impurities

USP 232 Revision 40, Parenteral 3

Element	Concentration	Volume	Matrix	Part #
Antimony	90 mg/kg	125 mL	5% HNO ₃ /tr. Tartaric Acid/tr. HF	USP-PARENT3
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	Part #
Arsenic	2 mg/kg	125 mL	5% HNO ₃	USP-INHL1
Cadmium	2 mg/kg			
Lead	5 mg/kg			
Mercury	1 mg/kg			

USP 232 Revision 40, Inhalation Mix 2A

Element	Concentration	Volume	Matrix	Part #
Cobalt	3 mg/kg	125 mL	2% HNO ₃	USP-INHL2A
Nickel	5 mg/kg			
Vanadium	1 mg/kg			

USP 232 Revision 40, Inhalation 2B, Mix 1

Element	Concentration	Volume	Matrix	Part #
Selenium	130 mg/kg	125 mL	2% HNO ₃	USP-INHL2B-1
Silver	7 mg/kg			
Thallium	8 mg/kg			

USP 232 Revision 40, Inhalation 2B, Mix 1

Element	Concentration	Volume	Matrix	Part #
Gold	1 mg/kg for each component	125 mL	5% HCl	USP-INHL2B-2
Iridium				
Osmium				
Palladium				
Platinum				
Rhodium				
Ruthenium				

USP 232 Revision 40, Inhalation Mix 3

Element	Concentration	Volume	Matrix	Part #
Antimony	20 mg/kg	125 mL	2% HNO ₃ /tr. Tartaric Acid/tr. HF	USP-INHL3
Barium	300 mg/kg			
Chromium	3 mg/kg			
Copper	30 mg/kg			
Lithium	25 mg/kg			
Molybdenum	10 mg/kg			
Tin	60 mg/kg			

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

Oral Elemental Impurities A

Element	Concentration	Volume	Matrix	Part #
Arsenic	1.5 mg/kg	125 mL	5% HNO ₃	USP-TXM2
Cadmium	25 mg/kg			
Lead	5 mg/kg			
Mercury	15 mg/kg			

Oral Elemental Impurities A

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

Precious Metal Impurities B (with Os)

Element	Concentration	Volume	Matrix	Part #
Iridium	100 mg/kg for each component	125 mL	15% HCl	USP-TXM3
Osmium				
Palladium				
Platinum				
Rhodium				
Ruthenium				

Precious Metal Impurities B (without Os)

Element	Concentration	Volume	Matrix	Part #
Iridium	100 mg/kg for each component	125 mL	15% HCl	USP-TXM4
Palladium				
Platinum				
Rhodium				
Ruthenium				

Oral/Parenteral Elemental Impurities C

Element	Concentration	Volume	Matrix	Part #
Copper	1,000 mg/kg	125 mL	5% HNO ₃	USP-TXM5
Molybdenum	100 mg/kg			
Nickel	500 mg/kg			
Vanadium	100 mg/kg			

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

Oral Elemental Impurities C

Element	Concentration	Volume	Matrix	Part #
Chromium	11,000 mg/kg	125 mL	5% HNO ₃	USP-TXM5A
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	Part #
Chromium	1,100 mg/kg	125 mL	5% HNO ₃	USP-TXM5B
Copper	300 mg/kg			
Molybdenum	1,500 mg/kg			
Nickel	20 mg/kg			
Vanadium	10 mg/kg			

Parenteral Elemental Impurities D

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

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Phone: 800.LAB.SPEX • 732.549.7144 • Fax: 732.603.9647
 CRMSales@spex.com • spexcertiprep.com

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