



Analytical Standard for ICH/Global Compliance

- Oral Elemental Impurities
- Precious Metal Impurities
- Elemental Impurities



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Analytical Standards for ICH/Global Compliance

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. ICH has produced a concept paper proposing a new guideline intended to provide a global policy for qualitatively and quantitatively limiting metal impurities in drug ingredients and finished products. The new proposed guideline (Q3D) would provide clarification of the requirements for metals, which are included in the ICH inorganic impurities classification. In the US, the FDA has pushed the pharmaceutical and nutraceutical industries to provide accurately quantifiable results. The current USP heavy metal procedure, USP <231>, is being replaced by the final proposed chapters for setting specifications, USP <232>, and methodology, USP <233>, for metal analysis in drugs, pharmaceutical substances and raw materials.

Spex CertiPrep is proud to offer a line of analytical standards for the analysis of trace metals in pharmaceutical materials. These standards can be used as a calibration or check standard to verify all component or dosage limits. Our 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.



Inorganic Certified Reference Materials



Designed for use with ICP-MS



Supplied with a Certificate of Analysis



ISO Accredited Standards

Analytical Standards for ICH/Global Compliance

Oral Elemental Impurities A

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

Precious Metal Impurities B (with Os)

Element	Concentration	Volume	Matrix	Part #
Iridium	100 mg/kg for each component in the mix	125 mL	15% HCl	ICH-TMX3
Osmium				
Palladium				
Platinum				
Rhodium				
Ruthenium				

Oral Elemental Impurities A

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

Table Header				
Element	Concentration	Volume	Matrix	Part #
Chromium	250 mg/kg	125 mL	5% HNO ₃	ICH-TXM7
Cobalt	100 mg/kg			
Copper	1,000 mg/kg			
Manganese	2,500 mg/kg			
Molybdenum	100 mg/kg			
Nickel	250 mg/kg			
Vanadium	100 mg/kg			

Table Header				
Element	Concentration	Volume	Matrix	Part #
Iron	13,000 mg/kg	125 mL	5% HNO ₃	ICH-TXM8
Zinc	13,000 mg/kg			

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