SPEX Europe®

Your Science Is Our Passion®

ICH/Global Compliance

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 Metals 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 Europe 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.

For additional product information, please visit www.eu.fishersci.com.

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-TXM3
Osmium				
Palladium				
Platinum				
Rhodium				
Ruthenium				

CERTIFIED REFERENCE MATERIALS

Since 1954, SPEX Europe is the industry leader in the CRM marketplace meeting the needs of laboratories worldwide with innovation and research. Accredited by A2LA to ISO/IEC 17025:2017 & ISO 17034:2016. Certified by UL-DQS, ISO 9001:2015.

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ICH/Global Compliance (cont'd)

Precious Metal Impurities B (without Os)				
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				

Elemental Impurities E				
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			

Elemental Impurities F				
Element	**Concentration**	**Volume**	**Matrix**	**Part #**
Iron	13,000 mg/kg	125 mL	5% HNO_3	ICH-TXM8
Zinc	13,000 mg/kg			

CAN'T FIND THE STANDARDS YOU ARE LOOKING FOR?

SPEX Europe can make custom standards to meet your exact needs. Contact your Fisher Scientific Sales Representative for a quote.

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