SPEX®

PHARMACEUTICAL STANDARDS

Reach Total Confidence in Pharmaceuticals Testing

MOST TRUSTED BRANDS IN ANALYTICAL REFERENCE MATERIALS

Our comprehensive experience in creating quality pharmaceutical standards will help you comply with the guidelines set by the United States Pharmacopeia (USP) and the International Conference of Harmonization (ICH) to provide accurate, quantifiable results for the metal analysis in drugs, pharmaceutical substances, and raw materials. These standards can be used as a calibration or check standard to verify Oral Daily Dose.

Featured Products:

- ICH/Global Compliance Standards
- Elemental Impurities
- Precious Metal Impurities
- Organic Volatile Impurities
- Residual Solvents

Pharmaceutical CRMs:

- Analytical Standards for USP <232>, <233>, <467>, and ICH/Global Compliance
- Provide accurate, quantifiable results for metal analysis
- Use with ICP-MS

SPEX.COM
+1.732.549.7144
+1.800.LAB.SPEX

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USP <232> and <233> Elemental Impurities

USP <232> outlines new limits and USP <233> outlines procedures 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.

Spex CertiPrep is proud to offer elemental impurities Certified Reference Materials (CRMs) for use in USP <232> and <233>. These standards can be used as a calibration or check standard to very oral daily dose PDE, parenteral component limit or parenteral daily dose PDE.

Oral Elemental Impurities A

Element	Concentration	Volume	Matrix	Part Number
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 (without Os)

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

Parenteral Elemental Impurities C

Element	Concentration	Volume	Matrix	Part Number
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			

Precious Metal Impurities B (with Os)

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

Oral Elemental Impurities C

Element	Concentration	Volume	Matrix	Part Number
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 D

Element	Concentration	Volume	Matrix	Part Number
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			

USP <467> Residual Solvents

The USP General Chapter <467> Residual Solvents is a method widely used for identifying and quantifying residual solvents when there is no information available on what solvents are likely to be present.

Spex CertiPrep now offers analytes in dimethyl sulfoxide for Class 1, Class 2 and Class 3 solvents. Our products are manufactured and verified by our QC department to validate the Certificate of Analysis which accompanies each product.

Oral Elemental Impurities C

Compound	CAS #	Concentration	Volume	Matrix	Part Number
Benzene	71-43-2	10,000 µg/mL	1 mL	Dimethyl sulfoxide	USP-RS-C1
Carbon tetrachloride	56-23-5	20,000 µg/mL			
1,2-Dichloroethane	107-06-2	25,000 µg/mL			
1,1-Dichloroethene	75-35-4	40,000 µg/mL			
1,1,1-Trichloroethane	71-55-6	50,000 µg/mL			

15 Organic Volatile Impurities: Class 2 Solvents

Compound	CAS #	Concentration	Volume	Matrix	Part Number
Acetonitrile	75-05-8	2,050 µg/mL	1 mL	Dimethyl sulfoxide	USP-RS-C2A
Chlorobenzene	108-90-7	1,800 µg/mL			
Cyclohexane	110-82-7	19,400 µg/mL			
cis-1,2-Dichloroethene	156-59-2	4,700 µg/mL			
trans-1,2-Dichloroethene	156-60-5	4,700 µg/mL			
1,4-Dioxane	123-91-1	1,900 µg/mL			
Ethylbenzene	100-41-4	1,840 µg/mL			
Methanol	67-56-1	15,000 µg/mL			
Methylcyclohexane	108-87-2	5,900 µg/mL			
Methylene Chloride	75-09-2	3,000 µg/mL			
Tetrahydrofuran	109-99-9	3,450 µg/mL			
Toluene	108-88-3	4,450 µg/mL			
m-Xylene	108-38-3	6,510 µg/mL			
o-Xylene	95-47-6	980 µg/mL			
p-Xylene	106-42-3	1,520 µg/mL			

8 Organic Volatile Impurities: Class 2 Solvents

Compound	CAS #	Concentration	Volume	Matrix	Part Number
Chloroform	67-66-3	60 µg/mL	1 mL	Dimethyl sulfoxide	USP-RS-C2B
1,2-Dimethoxyethane	110-71-4	100 µg/mL			
n-Hexane	110-54-3	290 µg/mL			
2-Hexanone	597-78-6	50 µg/mL			
Nitromethane	75-52-5	50 µg/mL			
Pyridine	110-86-1	200 µg/mL			
1,2,3,4-Tetrahydronaphthalene	119-64-2	100 µg/mL			
Trichloroethene	79-01-6	80 µg/mL			

USP <467> Residual Solvents (continued)

8 Organic Volatile Impurities: Class 2 Solvents

Compound	CAS #	Concentration	Volume	Matrix	Part Number
N,N-Dimethylacetamide	127-19-5	5,450 µg/mL	1 mL	Dimethyl sulfoxide	USP-RS-C2C
N,N-Dimethylformamide	68-12-2	4,400 µg/mL			
2-Ethoxyethanol	110-80-5	800 µg/mL			
Ethylene glycol	107-21-1	3,100 µg/mL			
Formamide	75-12-7	1,100 µg/mL			
2-Methoxyethanol	109-86-4	250 µg/mL			
1-Methyl-2-pyrrolidinone	872-50-4	2,650 µg/mL			
Tetramethylene sulfone	126-33-0	800 µg/mL			

8 Organic Volatile Impurities: Class 2 Solvents

Compound	CAS #	Concentration	Volume	Matrix	Part Number
Acetic acid	67-19-7	1,000 µg/mL for each component	1 mL	Dimethyl sulfoxide	USP-RS-C3B
Formic acid	64-18-6				

24 Organic Volatile Impurities: Class 3 Solvents

Compound	CAS #	Concentration	Volume	Matrix	Part Number
Acetone	67-64-1	1,000 µg/mL for each component	1 mL	Dimethyl sulfoxide	USP-RS-C3A
Anisole	100-66-3				
2-Butanone	78-93-3				
1-Butanol	71-36-3				
2-Butanol	78-92-2				
Butyl acetate	123-86-4				
tert-Butyl methyl ether	1634-04-4				
Ethanol	64-17-5				
Ether	60-29-7				
Ethyl acetate	141-78-6				
Ethyl formate	109-94-4				
n-Heptane	142-82-5				
Isobutyl acetate	110-19-0				
Isopropyl acetate	108-21-4				
Isopropyl benzene	98-82-8				
Methyl acetate	79-20-9				
3-Methyl-1-butanol	123-51-3				
4-Methyl-2-pentanone	108-10-1				
2-Methyl-1-propanol	78-83-1				
n-Pentane	109-66-0				
1-Pentanol	71-41-0				
1-Propanol	71-23-8				
2-Propanol (Isopropanol, Isopropyl alcohol)	67-63-0				
Propyl acetate	109-60-4				

ICH/Global Compliance Standards

The International Conference for Harmonization (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.

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.

Oral Elemental Impurities A

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

Precious Metal Impurities B (without Os)

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

Elemental Impurities F

Element	Concentration	Volume	Matrix	Part Number
Iron	13,000 mg/kg for each component	125 mL	5% HNO_3	ICH-TXM8
Zinc				

Precious Metal Impurities E

Element	Concentration	Volume	Matrix	Part Number
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			

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