

CERTIFIED
REFERENCE
MATERIALS

PHARMACEUTICAL STANDARDS for USP <467>, <232>, <233> & ICH

SPEX CertiPrep is renowned for high quality Certified Reference Materials and calibration standards for analytical spectroscopy and chromatography. We meet the needs of laboratories worldwide with innovation and research. We offer a full range of inorganic and organic CRMs.

SPEX CertiPrep's comprehensive experience in creating quality pharmaceutical standards will help you to comply with the guidelines set by the United States Pharmacopeia (USP) and the International Conference on Harmonization (ICH) to provide accurate, quantifiable results for the metal analysis in drugs, pharmaceutical substances and raw materials.

ORGANIC

Certified Reference Materials for:

HPLC | LC/MS | GC | GC/MS

- Over 4,000 single and multi component standards available
- Single component standards are offered in 1000 µg/mL
- Standards packaged in a variety of convenient sizes, including 1mL, 5mL and 10mL
- Concentration of components guaranteed

INORGANIC

Certified Reference Materials for:

ICP/MS | ICP | IC | AA | LC-ICP-MS

- Single element standards are offered in 1 µg/mL, 1,000 µg/mL and 10,000 µg/mL concentrations
- Standards packaged in a variety of convenient sizes, including 30mL, 125mL, 250mL, and 500mL bottles
- All standards and starting materials are triple checked for quality
- Up to 68 elemental impurities reported on our Inorganic Certificate of Analysis
- All standards are directly traceable to NIST SRMs, where available

SPEX CertiPrep is the industry leader for over 60 years in the CRM marketplace meeting the needs of laboratories worldwide with innovation and research.

Value of SPEX CertiPrep Certified Reference Materials

- Uncertainty of standard is reported on our Organic and Inorganic Certificates of Analysis
- Accuracy and stability of components are guaranteed
- Custom blends manufactured upon request, based on your individual needs
- Custom packaging available for your specific needs
- Manufactured by experienced chemists to ensure the highest quality

UL and A2LA Stamp of Approval

- Quality system complies with ISO 9001:2008 — Registered with UL
- Standards manufactured to meet the requirements of ISO 17025:2005 and ISO Guide 34-2009 — Accredited by A2LA



Accredited by A2LA for ISO 17025 and Guide 34,
and Certified by UL-DQS for ISO 9001.



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 35 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.

USP-RS-C1 (1 mL)

5 Component Mix in Dimethyl Sulfoxide

1,1,1-Trichloroethane	50000 µg/mL
1,1-Dichloroethene	40000 µg/mL
1,2-Dichloroethane	25000 µg/mL
Carbon tetrachloride	20000 µg/mL
Benzene	10000 µg/mL

USP-RS-C2A (1 mL)

15 Component Mix in Dimethyl Sulfoxide

Cyclohexane	19400 µg/mL
Methanol	15000 µg/mL
m-Xylene	6510 µg/mL
Methylcyclohexane	5900 µg/mL
cis-1,2-Dichloroethene	4700 µg/mL
trans-1,2-Dichloroethene	4700 µg/mL
Toluene	4450 µg/mL
Tetrahydrofuran	3450 µg/mL
Methylene chloride	3000 µg/mL
Acetonitrile	2050 µg/mL
1,4-Dioxane	1900 µg/mL
Ethylbenzene	1840 µg/mL
Chlorobenzene	1800 µg/mL
p-Xylene	1520 µg/mL
o-Xylene	980 µg/mL

USP-RS-C2B (1 mL)

8 Component Mix in Dimethyl Sulfoxide

n-Hexane	290 µg/mL
Pyridine	200 µg/mL
1,2,3,4-Tetrahydronaphthalene	100 µg/mL
1,2-Dimethoxyethane	100 µg/mL
Trichloroethene	80 µg/mL
Chloroform	60 µg/mL
2-Hexanone	50 µg/mL
Nitromethane	50 µg/mL

USP-RS-C2C (1 mL)

8 Component Mix in Dimethyl Sulfoxide

N,N-Dimethylacetamide	5450 µg/mL
N,N-Dimethylformamide	4400 µg/mL
Ethylene glyco	3100 µg/mL
1-Methyl-2-pyrrolidinone	2650 µg/mL
Formamide	1100 µg/mL
2-Ethoxyethanol	800 µg/mL
Tetramethylene sulfone	800 µg/mL
2-Methoxyethanol	250 µg/mL

USP-RS-C3B (1 mL)

2 Component Mix in Dimethyl Sulfoxide

Acetic Acid	1000 µg/mL
Formic acid	1000 µg/mL

USP-RS-C3A (1 mL)

24 Component Mix in Dimethyl Sulfoxide

1-Butanol	1000 µg/mL
1-Pentanol	1000 µg/mL
1-Propanol	1000 µg/mL
2-Butanol	1000 µg/mL
2-Butanone	1000 µg/mL
2-Methyl-1-propanol	1000 µg/mL
2-Propanol (Isopropanol, Isopropyl alcohol)	1000 µg/mL
3-Methyl-1-butanol	1000 µg/mL
4-Methyl-2-pentanone	1000 µg/mL
Acetone	1000 µg/mL
Anisole	1000 µg/mL
Butyl acetate	1000 µg/mL
Ethanol	1000 µg/mL
Ether	1000 µg/mL
Ethyl acetate	1000 µg/mL
Ethyl formate	1000 µg/mL
Isobutyl acetate	1000 µg/mL
Isopropyl acetate	1000 µg/mL
Isopropylbenzene	1000 µg/mL
Methyl acetate	1000 µg/mL
n-Heptane	1000 µg/mL
n-Pentane	1000 µg/mL
Propyl acetate	1000 µg/mL
tert-Butyl methyl ether	1000 µg/mL



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.

ICH-TXM2 (125 mL)	
Global/ICH Oral Elemental Impurities A	
4 Component Mix in 5% HNO ₃	
Cadmium	25 mg/kg
Mercury	15 mg/kg
Lead	5 mg/kg
Arsenic	1.5 mg/kg

ICH-TXM3 (125 mL)	
Global/ICH Precious Metal Impurities B (with Os)	
6 Component Mix in 5% HNO ₃	
Iridium	100 mg/kg
Osmium	100 mg/kg
Palladium	100 mg/kg
Platinum	100 mg/kg
Rhodium	100 mg/kg
Ruthenium	100 mg/kg

ICH-TXM4 (125 mL)	
Global/ICH Precious Metals Impurities B (without Os)	
5 Component Mix in 5% HNO ₃	
Iridium	100 mg/kg
Palladium	100 mg/kg
Platinum	100 mg/kg
Rhodium	100 mg/kg
Ruthenium	100 mg/kg

ICH-TXM7 (125 mL)	
Global/ICH Elemental Impurities E	
7 Component Mix in 5% HNO ₃	
Manganese	2500 mg/kg
Copper	1000 mg/kg
Chromium	250 mg/kg
Nickel	250 mg/kg
Cobalt	100 mg/kg
Molybdenum	100 mg/kg
Vanadium	100 mg/kg

ICH-TXM8 (125 mL)	
Global/ICH Elemental Impurities F	
2 Component Mix in 5% HNO ₃	
Iron	13000 mg/kg
Zinc	13000 mg/kg



USP <232> AND USP <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 Element Impurities Certified Reference Materials designed for use in USP <232> and USP <233>. 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.

USP-TXM2 (125 mL) USP Oral Elemental Impurities A 4 Component Mix in 5% HNO₃

Cadmium	25 mg/kg
Mercury	15 mg/kg
Lead	5 mg/kg
Arsenic	1.5 mg/kg

USP-TXM4 (125 mL) USP Precious Metals Impurities B (without Os) 5 Component Mix in 5% HNO₃

Iridium	100 mg/kg
Palladium	100 mg/kg
Platinum	100 mg/kg
Rhodium	100 mg/kg
Ruthenium	100 mg/kg

USP-TXM3 (125 mL) USP Precious Metal Impurities B (with Os) 6 Component Mix in 5% HNO₃

Iridium	100 mg/kg
Osmium	100 mg/kg
Palladium	100 mg/kg
Platinum	100 mg/kg
Rhodium	100 mg/kg
Ruthenium	100 mg/kg

USP-TXM5 (125 mL) USP Oral/Parenteral Elemental Impurities C 4 Component Mix in 5% HNO₃

Copper	1000 mg/kg
Nickel	500 mg/kg
Molybdenum	100 mg/kg
Vanadium	100 mg/kg

