

# Pharmaceutical Analysis Standards

## USP Standards

As a part of our United States Pharmacopeia (USP) compliant offering, we provide calibration and check standards for the analysis of metals in drugs, pharmaceutical substances and raw materials to verify Oral Daily Dose PDE, Parenteral Component Limit and Parenteral Daily Dose PDE.

Our trace metal USP standards can be used to calibrate Arsenic, Cadmium, Lead and Mercury, the four toxic metals as part of the USP regulations. When you couple our accurate and reliable USP standards with your ICP-MS you will remain compliant with the new and changing regulations.

## ICH Standards

In conjunction with our United States Pharmacopeia (USP) calibration standards, we offer six calibration standards for the analysis of metals in pharmaceutical materials and products following the International Conference on Harmonization (ICH) guidelines.

The ICH standards verify Elemental Impurities, Precious Metals Impurities and Parenteral Elemental Impurities. Couple our accurate and reliable ICH standards with your ICP-MS and you will remain compliant with the new and changing regulations.



## USP and ICH Standards

Matrix	Content	Volume	Part No.
<b>ICH Elemental Impurities Standards Kit – Oral PDEs</b> Kit Includes:			<b>N9304361</b>
5% HNO <sub>3</sub> / 2% HCl	ICH Class 1 Elements + TI – Oral PDE: 30 µg/mL Hg 15 µg/mL As 8 µg/mL TI 5 µg/mL Cd, Pb	125 mL	<b>N9304362</b>
2% HNO <sub>3</sub>	ICH Class 2A Elements – Oral and Parenteral PDEs: 200 µg/mL Ni 100 µg/mL V 50 µg/mL Co	125 mL	<b>N9304363</b>
2% HCl	100 µg/mL Au	125 mL	<b>N9303728</b>
15% HCl	ICH Class 2B Precious Metal Elements (no Os) – All PDEs: 100 µg/mL Ir, Pd, Pt, Rh, Ru	125 mL	<b>N9304364</b>
2% HNO <sub>3</sub>	ICH Class 2B Se & Ag – Oral PDE: 150 µg/mL Ag, Se	125 mL	<b>N9304365</b>
5% HNO <sub>3</sub> /trace Tartaric Acid/ trace HF	ICH Class 3 Elements – Oral PDEs: 1100 µg/mL Cr 600 µg/mL Sn 300 µg/mL Cu, Mo 140 µg/mL Ba 120 µg/mL Sb 55 µg/mL Li	125 mL	<b>N9304366</b>
2% HNO <sub>3</sub>	Internal Standards – All PDEs: 50 µg/mL Ge 20 µg/mL Ga 1 µg/mL In, Tb	125 mL	<b>N9304367</b>

Matrix	Content	Volume	Part No.
<b>ICH Elemental Impurities Standards Kit – Parenteral PDEs</b> Kit Includes:			<b>N9304368</b>
5% HNO <sub>3</sub> / 2% HCl	ICH Class 1 Elements + TI – Parenteral PDE: 15 µg/mL As 8 µg/mL TI 5 µg/mL Pb 3 µg/mL Hg 2 µg/mL Cd	125 mL	<b>N9304369</b>
2% HNO <sub>3</sub>	ICH Class 2A Elements – Oral and Parenteral PDEs: 200 µg/mL Ni 100 µg/mL V 50 µg/mL Co	125 mL	<b>N9304363</b>
2% HCl	100 µg/mL Au	125 mL	<b>N9303728</b>
15% HCl	ICH Class 2B Precious Metal Elements (no Os) – All PDEs: 100 µg/mL Ir, Pd, Pt, Rh, Ru	125 mL	<b>N9304364</b>
2% HNO <sub>3</sub>	ICH Class 2B Se & Ag – Parenteral PDE: 80 µg/mL Se 10 µg/mL Ag	125 mL	<b>N9304372</b>
2% HNO <sub>3</sub> /trace Tartaric Acid/ trace HF	ICH Class 3 Elements – Parenteral PDEs: 150 µg/mL Mo 110 µg/mL Cr 60 µg/mL Sn 30 µg/mL Cu 70 µg/mL Ba 25 µg/mL Li 9 µg/mL Sb	125 mL	<b>N9304373</b>
2% HNO <sub>3</sub>	Internal Standards – All PDEs: 50 µg/mL Ge 20 µg/mL Ga 1 µg/mL In, Tb	125 mL	<b>N9304367</b>