



Metal standards for the pharmaceutical industry

Regulatory requirements for inorganic impurities are being tightened. Be prepared and get your reference standards for metals from LGC Standards.

Although changes to the USP-NF General Chapter <232> “Elemental Impurities – Limits” and <233> “Elemental Impurities – Procedures” have been delayed, the proposed changes highlight a valid concern that the analytical techniques in place are inadequate for the analysis of inorganic impurities in drug substances and products in the modern world. The former tests in General Chapter <231> are based on an unspecific sulfide precipitation and will be replaced by instrumental analytical methods like ICP-OES and ICP-MS. Limits will be given not only for the single metals, but will also take into account the different specifications of certain elements.

LGC Standards provides the perfect range for your metals residues analysis, and will facilitate greater analytical certainty. All products are prepared from high purity raw materials, acids and 18 Mohm Di water, assayed by NIST HP-ICP-AES method, and purity is confirmed by ICP-MS. Furthermore, they are manufactured under ISO 9001 and ISO Guide 34, certified under ISO/IEC 17025 and accompanied by a NIST-traceable COA. LGC Standards can also provide you with single element standards for your specific needs.

Metal standards

USP1-OI-100	USP class 1 oral impurities standard	As @ 1.5 mg/kg, Cd @ 25 mg/kg, Hg @ 15 mg/kg, and Pb @ 5 mg/kg in 5% HNO ₃ . 100mL bottle
USP1-PI-100	USP class 1 parenteral impurities standard	As @ 1.5 mg/kg, Cd @ 2.5 mg/kg, Hg @ 1.5 mg/kg, and Pb @ 5 mg/kg in 5% HNO ₃ . 100mL bottle
USP2-OPPM-100	USP class 2 oral & parenteral precious metals standard	Ir, Os, Pd, Pt, Rh, Ru @ 100 mg/kg in 20% HCl. 100mL bottle
USP2-OPI-100	USP class 2 oral & parenteral impurities standard	Cr, Mo, and V @ 10 mg/kg, Ni @ 50 mg/kg, and Cu @ 100 mg/kg in 5% HNO ₃ . 100mL bottle
USP1-OPHG-100	USP class 1 oral & parenteral mercury standard	Hg @ 10 mg/kg in 5% HNO ₃ . 100mL bottle
LSAU-100	Gold stabilizer for mercury determination	Au @ 100 µg/mL in 5% HCl. 100mL bottle

For further information, or if you require substances or materials not currently listed please contact one of our local sales offices.

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