



Elemental impurity standards USP <232>/ICH Q3D



Trace metal impurities pose risks to human health as well as the quality and efficacy of pharmaceutical products. Recent changes to regulatory guidelines require the specific quantitative analysis of pharmaceutical products using ICP-OES or ICP-MS.

USP <232> Elemental Impurities – Limits, USP <233> Elemental Impurities – Procedures, and Ph. Eur. Chapter 5.2 align with ICH Q3D.

LGC has developed a set of certified reference materials (CRMs) to perform each of the requirements for USP <232>/ICH Q3D compliance that are traceable directly to the National Institute of Standards and Technology (NIST) SRMs.

Each of the standards that LGC produces for USP <232> and ICH Q3D compliance meets the stringent requirements of ISO 17034 and ships with a comprehensive Certificate of Analysis (CofA). We offer a complete CRM kit for the entire range of target elements including an internal standard optimized for this application. LGC Standards can also provide you with single element standards for your specific needs.

LGC's reference standards for pharmaceutical testing include more than 5,000 APIs, their impurities, excipients and primary reference standards.

CRM kit for metal impurities

Kit	Components	Volume (mL)	Product code
USP 232 & ICH Q3D kit	USP/ICH Oral target elements: Standard A, Standard B, Standard C, Standard D, Pharma internal standard	5 x 100	VHG-ICH-USP-KIT-5X100

Oral target element CRMs

Name	Elements	Matrix	Volume (mL)	Product code
USP/ICH Oral target elements Standard A	Hg @ 30; As @ 15; Cd, Pb @ 5 µg/mL	2% HNO ₃	100	VHG-ICH-USP-TELA-100
USP/ICH Oral target elements Standard AZ	As @ 15; Cd, Pb @ 5 µg/mL	2% HNO ₃	100	VHG-ICH-USP-TELAZ-100
USP/ICH Oral target elements Standard B	Ni @ 200; Ag, Se @ 150; V @ 100; Co @ 50; Tl @ 8 µg/mL	2% HNO ₃	100	VHG-ICH-USP-TELB-100
USP/ICH Oral target elements Standard C	Au, Ir, Os, Pd, Pt, Rh, Ru @ 100 µg/mL	15% HCl	100	VHG-ICH-USP-TELC-100
USP/ICH Oral Target Elements Standard CZ	Ir, Pd, Pt, Rh, Ru @ 100 µg/mL	5% HCl	100	VHG-ICH-USP-TELCZ-100
USP/ICH Oral target elements Standard D	Cr @ 11,000; Sn @ 6000; Cu, Mo @ 3000; Ba @ 1400; Sb @ 1200; Li @ 550 µg/mL	5% HNO ₃ , tr. HF	100	VHG-ICH-USP-TELD-100
Pharma internal standard solution	Te @ 25; Sc @ 10; Ge, In, Lu, Bi @ 5 µg/mL	2% HNO ₃ , tr. HF	100	VHG-PHARM-IS1-100

Parenteral target element CRMs

Name	Elements	Matrix	Volume (mL)	Product code
USP/ICH Class 1&2A Parenteral target elements	Ni @ 20; As @ 15; V @ 10; Co, Pb @ 5; Hg @ 3; Cd @ 2 µg/mL	2% HNO ₃	100	VHG-ICH-USP-TELE-100
USP/ICH Parenteral combined-1 target elements	Mo @ 1500, Cr @ 1100, Ba @ 700, Sn @ 600, Cu @ 300, Li @ 250, Sb @ 90, Se @ 80, Ag @ 10, Tl @ 8 µg/mL	5% HNO ₃ , tr. HF	100	VHG-ICH-USP-TELF-100
USP/ICH Parenteral combined-2 target elements	Au @ 100; Ir, Os, Pd, Pt, Rh, Ru @ 10 µg/mL	15% HCl	100	VHG-ICH-USP-TELG-100

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