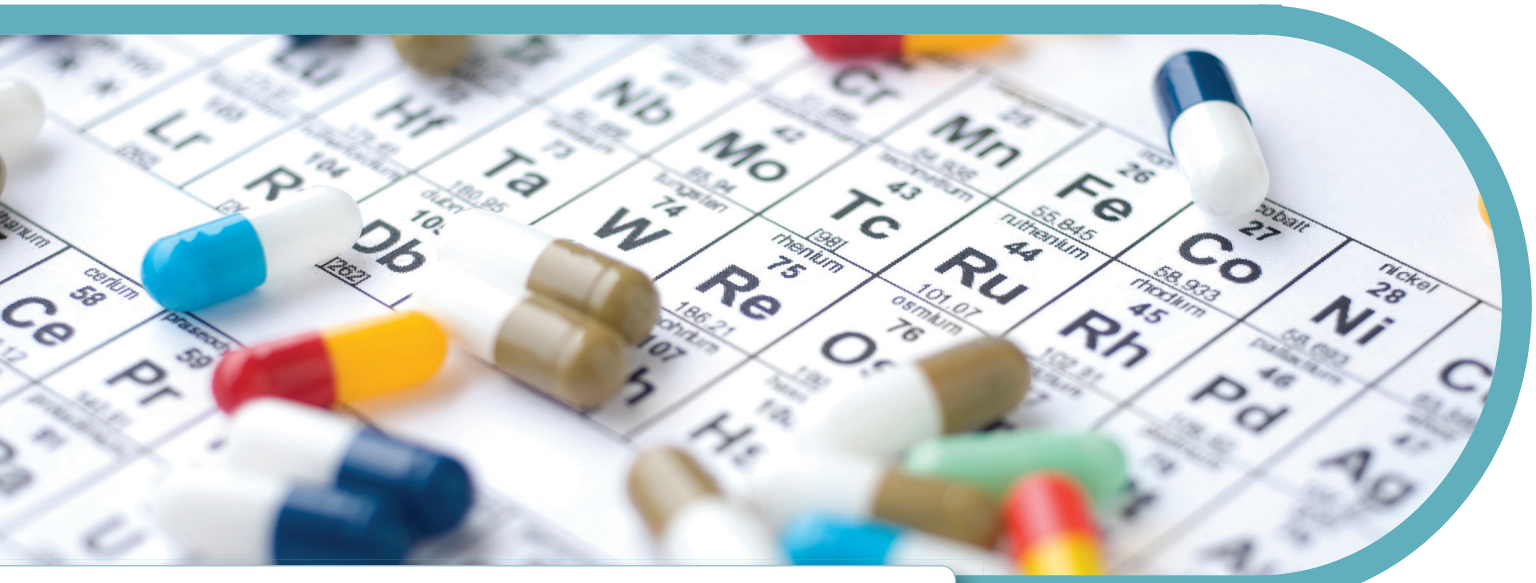
ICH Q3D/USP <232>
Elemental impurities standards

ICH Q3D and USP <232> have been unified and finalized to provide method protocols and regulatory requirements for measurement of inorganic impurities in pharmaceutical products. LGC has developed a suite of certified reference materials (CRMs) to help ensure that pharmaceutical products do not exceed safe limits for metals.

Official regulatory limits for inorganic impurities in pharmaceutical products using ICP-MS or ICP-AES have been established and made official in the guidelines ICH Q3D and USP <232> “Elemental Impurities – Limits” and <233> “Elemental Impurities – Procedures”. They greatly advance the techniques for the analysis of metal impurities and toxic elements and supersede the antiquated analytical protocols of the past.

LGC provides the perfect ranges of elemental impurities CRMs to meet the method’s Permissible Daily Exposure (PDE) levels required. LGC also offers an internal standard solution which is optimized for best ICP-MS results with these sample types. These products are available in a cost effective and conveniently packaged kit.

LGC prepares all products from high purity raw materials, acids and 18 Mohm DI water. Total confidence in certified concentrations is ensured by our industry-leading QA and assay procedure known as the NIST high performance ICP-AES protocol. The purity of the CRMs is verified by ICP-MS. Furthermore, they are manufactured under ISO 9001 and ISO Guide 34, and certified under ISO/IEC 17025. LGC elemental impurity reference standards are accompanied by a NIST-traceable certificate of analysis (COA). LGC can also provide you with single element standards for your specific needs–whether they are impurities within the scope of the method or additional elements.



In-house expertise

Please do not hesitate to contact your LGC local office for technical assistance. LGC has the laboratory know-how to guide you through implementation of calibrants and standards for your ICH/USP testing needs.

Multi-element metal impurity CRMs for ICH Q3D & USP 232				
Name	**Elements**	**Matrix**	**Volume (mL)**	**Product code**
ICH/USP Oral target elements standard A	Hg @ 30; As @ 15; Cd, Pb @ 5 µg/mL	2% HNO_3	100	VHG-ICH-USP-TELA-100
ICH/USP 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
ICH/USP Oral target elements standard C	Au, Ir, Os, Pd, Pt, Rh, Ru @ 100 µg/mL	5% HCl	100	VHG-ICH-USP-TELC-100
ICH/USP 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

CRM kit for metal impurities for ICH Q3D & USP 232		
Kit	**Product code**	**Size**
ICH Q3D & USP 232 kit	VHG-ICH-USP-KIT-5X100	5 x 100 mL

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