Simplify Testing of Elemental Impurities in Pharmaceuticals with Agilent's Certified Reference Materials

ICH Q3D/USP <233> Elemental Impurities Portfolio

New limits for elemental impurities in pharmaceutical materials and dietary supplements have been released by the United States Pharmacopeia (USP) – Chapter USP <232>.

Agilent's ICH Q3D/USP <233> Elemental Impurities Portfolio includes reference material kits for oral and parenteral routes. These kits consist of certified reference materials (CRMs) that sort elements by ICH/USP class, chemical compatibility, and the relative mandated concentrations. This eliminates the need for analysts to prepare their own calibration standards from single-element standards—reducing preparation time and minimizing errors.

Recently, US Pharmacopeia has changed their guidelines for USP <232>. They have increased the limits for gold and silver. Agilent has updated their kits and mixes to reflect these new guidelines. These kits and submixes include:

- The perfect range of elemental impurities CRMs to meet the method's oral and parenteral Permissible Daily Exposure (PDE) levels.
- An Internal Standard Solution which is optimized for best ICP-MS/ICP-OES results with common pharmaceutical sample types.
- Manufactured in an ISO 17034 accredited facility and certified in an ISO/IEC 17025 testing laboratory.
- A Certificate of Analysis confirming actual concentrations, measurement uncertainty, and NIST traceability.

Agilent's ICP-OES and ICP-MS instrumentation also provides the ideal capabilities for determining inorganic contaminants to ICH Q3D and USP<233> requirements. Together with the ICH/USP <233> impurities standards portfolio, Agilent offers a complete solution supporting a transition to the new methods for elemental impurities in pharmaceuticals.

Find the full ICH/USP <233> impurities standards portfolio here:

www.agilent.com/chem/usp-standards

For more information contact your local Agilent representative or visit:
www.agilent.com/chem/standards

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Ordering information

Description	Number of analytes	Contains	Matrix	Volume (mL)	Part number
ICH Q3D and USP 232 Orals Kit, 5 x 100 mL		5190-9766, 5190-9767, 5191-4555, 5190-9769, 5190-9770		5 x 100	5191-4553
ICH/USP Target Elements Standard A	4	As @ 15 µg/mL Cd, Pb @ 5 µg/mL Hg @ 30 µg/mL	2% HNO_3	100	5190-9766
ICH/USP Oral Target Elements Standard B	6	Tl @ 8 µg/mL Co @ 50 µg/mL V @ 100 µg/mL V Ag, Se @ 150 µg/mL Ni @ 200 µg/mL	2% HNO_3	100	5190-9767
ICH/USP Oral Target Elements Standard C	7	Ir, Os, Pd, Pt, Rh, Ru @ 100 µg/mL Au @ 300 µg/mL	15% HCl	100	5191-4555
ICH/USP Oral Target Elements Standard D	7	Li @ 550 µg/L Sb @1200 µg/mL Ba @ 1400 µg/mL Ba Cu, Mo @ 3000 µg/mL Sn @ 6000 µg/mL Cr @11000 µg/mL	5% HNO_3 trace HF	100	5190-9769
Pharma Internal Standard 1	6	Bi, Ge, In, Lu @ 5 µg/mL Sc @ 10 µg/mL Te @ 25 µg/mL	2% HNO_3 trace HF	100	5190-9770
ICH/USP 232 Parenteral kit, 4 x 100 mL		5191-4533, 5191-4557, 5191-4558, 5191-9770		4 x 100	5191-4556
ICH/USP 232 Class 1 and 2 Parenteral Elements	7	Cd @ 2 µg/mL Hg @ 3 µg/mL Co, Pb @ 5 µg/mL V @ 10 µg/mL As @ 15 µg/mL Ni @ 20 µg/mL	2% HNO_3	100	5191-4533
ICH/USP 232, Parenteral Combined 1	10	Tl @ 8 µg/mL Ag @ 15 µg/mL Se @ 80 µg/mL Sb @ 90 µg/mL Li @ 250 µg/mL Cu @ 300 µg/mL Sn @ 600 µg/mL Ba @ 700 µg/mL Cr @ 1100 µg/mL Mo @ 1500 µg/mL	5% HNO_3 trace HF	100	5191-4557
ICH/USP 232 Parenteral Combined 2	7	Ir, Os, Pd, Pt, Rh, Ru @ 10 µg/mL Au @ 15 µg/mL	15% HCl	100	5191-4558
Pharma Internal Standard 1	6	Bi, Ge, In, Lu @ 5 µg/mL Sc @ 10 µg/mL Te @ 25 µg/mL	2% HNO_3 trace HF	100	5190-9770

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