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

ICH Q3D/USP <233> Elemental Impurities Kits

New limits for elemental impurities in pharmaceutical materials and dietary supplements have been released by the United States Pharmacopeia (USP) – Chapters USP <232> and <233>, and the International Council on Harmonization (ICH, Q3D).

The procedures to quantify elemental impurities (USP <233>) specify ICP-OES and ICP-MS as the reference analytical methods for compendial procedures. These replace the archaic colorimetric test as previously defined in USP Chapter <231>, 'heavy metals analysis'. The new chapters with new methodologies extend the list of analytes, reduce the maximum permitted exposure limits and take account of the route of exposure (e.g., oral, parenteral, and inhalational).

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.

Part Number	Oral Kits	Route of Exposure
5190-9771	ICH Q3D/USP<233> Orals Impurity Kits (Includes one each of 5190-9766, 5190-9767, 5190-9768, 5190-9769, 5190-9770)	Oral
5190-9766	ICH/USP Target Elements Standard A	Oral
5190-9767	ICH/USP Target Elements Standard B	Oral
5190-9768	ICH/USP Target Elements Standard C	Oral
5190-9769	ICH/USP Target Elements Standard D	Oral
5191-4536	ICH Q3D/USP<233> Parenteral Impurity Kits (Includes one each of 5191-4533, 5191-4534, 5191-4535, 5190-9770)	Parenteral
5191-4533	ICH/USP 232 Class1&2 Parenteral Elements	Parenteral
5191-4534	ICH/USP 232 Parenteral Combined-1	Parenteral
5191-4535	ICH/USP 232 Parenteral Combined-1	Parenteral
5190-9770	Pharma Internal Standard 1	Oral/Parenteral

These kits include:

- The perfect range of elemental impurities CRMs to meet the method's oral or 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 kits, Agilent offers a complete solution supporting a transition to the new methods for elemental impurities in pharmaceuticals.

For more information contact your local Agilent representative or visit:
www.agilent.com/en/solutions/pharma-biopharma/small-molecules/manufacturing-quality-control/elemental-analysis#relatedProducts

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