SIMPLIFY TESTING OF ELEMENTAL IMPURITIES IN PHARMACEUTICALS WITH AGILENT'S CERTIFIED REFERENCE MATERIALS KIT

ICH Q3D/USP <233> Elemental Impurities Kit

New limits for elemental impurities in pharmaceutical materials and dietary supplements have been released by the United States Pharmacopeia (USP) – Chapters USP <232> and <2232>, 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 Kit consists of five 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.

This kit includes:

- The perfect range of elemental impurities CRMs to meet the method's oral 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 Guide 34 certified 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 Q3D/USP<233> impurities kit, Agilent offers a complete solution supporting transition to the new methods for elemental impurities in pharmaceuticals.

Part Number	Product Description	Product Contents	Matrix	Volume
5190-9771	**ICH Q3D/USP<233> impurities Kit**	**Includes 1 of each of the following standards (A, B, C and D) plus the Internal Standard**		
5190-9766	ICH/USP Target Elements Standard A	Hg @ 30; As @ 15; Cd, Pb @ 5 µg/mL	2% HNO_3	100mL
5190-9767	ICH/USP Target Elements Standard B	Ni @ 200; Ag, Se @ 150; V @ 100; Tl @ 8; Co @ 50 µg/mL	2% HNO_3	100mL
5190-9768	ICH/USP Target Elements Standard C	Au, Ir, Os, Pd, Pt, Rh, Ru @ 100 µg/mL	15% HCl	100mL
5190-9769	ICH/USP Target Elements Standard D	Cr @ 11,000; Sn @ 6000; Cu, Mo @ 3000; Ba @ 1400; Sb @ 1200; Li @ 550 µg/mL	5% HNO_3/ trace HF	100mL
5190-9770	Pharma Internal Standard 1	Te @ 25; Sc @ 10; Ge, In, Lu, Bi @ 5 µg/mL	2% HNO_3/ trace HF	100mL

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

Published May 26, 2017
5991-8177EN

Agilent Technologies