

Agilent Product Name: ICH/USP Target Elements Standard D

Agilent Part No: 5190-9769

Lot No: 0004517623

Product Specifications

Analyte	Starting Material	CAS #	Certified Conc.	Analyte	Starting Material	CAS #	Certified Conc.
Ba	Ba(NO ₃) ₂	10022-31-8	1400 ± 7 µg/mL	Mo	Mo	7439-98-7	3000 ± 15 µg/mL
Cr	Cr(NO ₃) ₃	13548-38-4	11,000 ± 55 µg/mL	Sb	Sb	7440-36-0	1204 ± 6 µg/mL
Cu	Cu	7440-50-8	3000 ± 15 µg/mL	Sn	Sn	7440-31-5	6000 ± 30 µg/mL
Li	Li ₂ CO ₃	554-13-2	550.0 ± 2.8 µg/mL				

Matrix: 5% HNO₃/tr. HF

Intended Use: This solution is intended for use as a certified reference material or calibration standard for inductively coupled plasma optical emission spectroscopy (ICP-OES), or inductively coupled plasma mass spectrometry (ICP-MS). It is designed to meet the needs of the analysis of elemental impurities in pharmaceutical drug products based on guidelines set in ICH Q3D, chapters USP <232> and USP <233>.

Certification & Traceability: This CRM was manufactured under a quality management system that is accredited to **ISO Guide 34, ISO/IEC 17025**, and registered to **ISO 9001**. This CRM was prepared to the certified concentrations shown above by gravimetric methods using single-element concentrates that were certified using the "High Performance ICP-OES" protocol developed by NIST and are directly traceable to the NIST SRMs listed below. This solution was stabilized using high purity nitric acid (HNO₃), trace hydrofluoric acid (HF) and diluted with filtered (0.22µm), 18 M-ohm deionized water. The balances used in the preparation of this CRM are calibrated regularly with traceability to NIST. All volumetric dilutions are performed in Class A calibrated glassware. The certified concentrations were determined based upon gravimetric procedures. Secondary verification of the certified concentrations was performed using ICP-OES that was calibrated and/or referenced against NIST SRMs: 3104a, 3112a, 3114, 3129a, 3134, 3102a and 3161a. The uncertainty associated with each certified concentration represents the expanded uncertainty at the 95% confidence level using a coverage factor of k=2.

Uncertified Values:

Density: 1.104 g/mL

ICP-MS was used to determine trace metal concentrations for this product (nd = not determined).

Trace Concentrations (µg/L)

Ag	<0.5	Ce	<0.2	Gd	<0.2	Lu	<0.2	Pb	<1	Se	<2	Tl	<0.5
Al	<2	Co	<1	Ge	<0.5	Mg	<5	Pd	<0.5	Si	<1000	Tm	<0.2
As	<2	Cs	<0.5	Hf	119	Mn	<1	Pr	<0.2	Sm	<0.2	U	<0.5
Au	<0.5	Cr	MAJOR	Hg	<0.5	Mo	MAJOR	Pt	<0.5	Sn	MAJOR	V	<1
B	<5	Cu	MAJOR	Ho	<0.2	Na	<25	Rb	<0.5	Sr	<1	W	<0.5
Ba	MAJOR	Dy	<0.2	In	nd	Nb	<0.5	Re	9	Ta	2	Y	<0.5
Be	<0.5	Er	<0.2	Ir	<0.2	Nd	<0.2	Rh	<0.5	Tb	<0.5	Yb	<0.2
Bi	<0.2	Eu	1	K	<25	Ni	<2	Ru	<0.5	Te	<1	Zn	<2
Ca	<25	Fe	<10	La	<0.5	Os	<0.5	Sb	MAJOR	Th	<0.5	Zr	138
Cd	<0.5	Ga	<0.5	Li	MAJOR	P	<100	Sc	<5	Ti	<2		

Instructions for Use: Agilent Technologies recommends that the solution be thoroughly mixed by repeated shaking or swirling of the bottle immediately prior to use. To achieve the highest accuracy the analyst should: (1) use only pre-cleaned containers and transferware, (2) avoid pipetting directly from the CRM's original container, (3) use a minimum sub-sample size of 500µL, (4) make dilutions using calibrated balances or certified volumetric class A flasks and pipettes, (5) dilute to volume using the same matrix as the original CRM, and (6) never pour used product back into the original container. The solution should be kept tightly capped. Store at controlled room temperature per USP 35 (10.30.60). Do not freeze, heat, or expose to direct sunlight. Minimize exposure to moisture or high humidity.

Period of Validity: Agilent Technologies ensures the accuracy of this solution until the expiration date shown below, provided the instructions for use are followed. During the period of validity, the purchaser will be notified if this product is recalled due to any significant changes in the stability of the solution.

Sample lot approver:

Julie M. MacIntyre

QA Manager

Date of release: 22 March 2018

Date of expiration: 5 May 2019