CERTIFICATE OF ANALYSIS

LGC Quality Product

Multi-Element Aqueous CRM

ICH/USP Oral Target Elements Standard D — Product #: VHG-ICH-USP-TELD-100

Matrix: 5% HNO_3, tr. HF — Lot #: 1030985-1

Element	Certified Concentration & Uncertainty (w/v)	Certified Concentration & Uncertainty (w/w)
Ba	1400 ± 7 µg/mL	1257 ± 6 µg/g
Cr	11,000 ± 55 µg/mL	9878 ± 49 µg/g
Cu	3000 ± 15 µg/mL	2694 ± 13 µg/g
Li	550.0 ± 2.8 µg/mL	493.9 ± 2.5 µg/g
Mo	3000 ± 15 µg/mL	2694 ± 13 µg/g
Sb	1200 ± 6 µg/mL	1078 ± 5 µg/g
Sn	6000 ± 30 µg/mL	5388 ± 27 µg/g

Intended Use: This solution is intended for use as a certified reference material (CRM) 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: LGC CRMs are manufactured, processed, and certified under a quality management system that is registered/accredited to **ISO 9001**, **ISO 17034**, and **ISO/IEC 17025**. 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 **NIST SRMs (see reverse side)**. The solution was stabilized using high purity nitric acid (HNO_3), trace hydrofluoric acid (HF), and diluted with filtered (0.22 µm), 18 M-ohm deionized water. The balances used in the preparation of LGC CRMs are calibrated regularly with traceability to NIST, using a calibration provider that is accredited to ISO/IEC 17025 by a mutually recognized accreditation body. All volumetric dilutions are performed in Class A calibrated glassware. The certified concentrations were determined by LGC based upon gravimetric procedures. Secondary verification of the certified concentrations was performed by LGC using ICP-OES that was calibrated and/or referenced against **NIST SRMs (see reverse side)**. 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: ICP-MS was used to determine trace metal concentrations for this product (nd = not determined).

Trace Concentrations (µg/L)

Ag	<0.5	Co	<1	Ge	<0.5	Lu	<0.2	P	<100	Sb	MAJOR	Te	<1
Al	<2	Cs	<0.5	Hf	2	Mg	<5	Pb	<1	Sc	<5	Ti	9
As	<2	Cr	MAJOR	Hg	<0.5	Mn	<1	Pd	<0.5	Se	<2	Tl	<0.5
Au	<0.5	Cu	MAJOR	Ho	<0.2	Mo	MAJOR	Pr	<0.2	Si	<100	Tm	<0.2
B	<5	Dy	<0.2	In	nd	Na	<25	Pt	<0.5	Sm	<0.2	V	<1
Ba	MAJOR	Er	<0.2	Ir	<0.2	Nb	<0.5	Rb	<0.5	Sn	MAJOR	W	3
Bi	<0.2	Eu	0.9	K	<25	Nd	<0.2	Re	<0.2	Sr	<1	Y	<0.5
Ca	<25	Fe	<10	La	<0.5	Ni	63	Rh	<0.5	Ta	<0.5	Yb	<0.2
Cd	17	Ga	<0.5	Li	MAJOR	Os	<0.5	Ru	<0.5	Tb	<0.5	Zn	4
Ce	<0.2	Gd	<0.2										

Period of Validity: LGC ensures the accuracy of this solution for **12 months** from the certification 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.

Chuck Goudreau, Certifying Officer

See Exp. Date on Container
Certification Date

ACCREDITED
REFERENCE MATERIALS PRODUCER CERT #2848.02
CHEMICAL TESTING CERT #2848.01

LGC waives all responsibility for any damages resulting from the usage and/or implementation of the products/data described herein.

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Instructions for Use: We recommend 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) not pipette directly from the CRM's original container, (3) never pour used product back into the original container, (4) make dilutions using calibrated balances or certified class A volumetric flasks and pipettes, (5) use a minimum sub-sample size of 500 µL, and (6) dilute with the same matrix as the original CRM or other chemically suitable matrix. The solution should be kept tightly capped and stored at a controlled room temperature per USP 35 (10.30.60). Do not freeze, heat, or immerse the bottle or its contents, and avoid exposure to direct sunlight or moisture.

Health and Safety Information: Refer to the Safety Data Sheet (SDS), which can be obtained at lgcstandards.com.

Homogeneity: This solution was determined to be homogeneous by procedures consistent with the requirements of ISO 17034 and ISO Guide 35. Replicate samples of the finished solution were analyzed to confirm its homogeneity, in accordance with VHG QSP 6-13 Assessment of Homogeneity and Stability. To ensure homogeneity, users should not take a smaller sub-sample than specified in the Instructions for Use, as doing so will invalidate the certified values and uncertainties.

Quality Manual Rev: No. 5, 03/01/2013

Further Information: Please contact LGC for further information about this CRM.

Quality Certifications: This CRM was prepared under a quality management system that is registered/accredited to the following:

- ISO 9001 – Quality Management Systems – Requirements (Registrar: TUV NORD)
- ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories
- ISO 17034 – General Requirements for the Competence of Reference Material Producers
    - ISO 17034 references additional requirements specified in ISO Guide 31 and ISO Guide 35.

LGC CRMs are traceable to the following NIST SRMs:

Analyte	Aq. SRM	MO SRM		Analyte	Aq. SRM	MO SRM		Analyte	Aq. SRM	MO SRM
Ag	3151	1077a		Hf	3122	—		S	3154	2770
Al	3101a	1075a		Hg	3133	3133		Sb	3102a	3102a
As	3103a	3103a		Ho	3123a	—		Sc	3148a	3148a
Au	3121	—		In	3124a	3124a		Se	3149	3149
B	3107	3107		K	3141a	3141a		Si	3150	1066a
Ba	3104a	1051b		La	3127a	3127a		Sm	3147a	—
Be	3105a	3105a		Li	3129a	3129a		Sn	3161a	1057b
Bi	3106	3106		Lu	3130a	—		SO_4^{-2}	3181	—
Br^-	3184	—		Mg	3131a	3131a		Sr	3153a	3153a
Ca	3109a	3109a		Mn	3132	3132		Ta	3155	—
Cd	3108	1053a		Mo	3134	3134		Tb	3157a	—
Ce	3110	3110		Na	3152a	3152a		Te	3156	—
Cl^-	3182	1818a		Nb	3137	—		Th	3159	—
Co	3113	3113		Nd	3135a	—		Ti	3162a	3162a
Cr	3112a	1078b		Ni	3136	1065b		Tl	3158	3158
Cs	3111a	—		NO_3^-	3185	—		Tm	3160a	—
Cu	3114	1080a		P	3139a	3139a		U	3164	—
Dy	3115a	—		Pb	3128	3128		V	3165	1052b
Er	3116a	—		Pd	3138	—		W	3163	3163
Eu	3117a	—		PO_4^{-3}	3186	—		Y	3167a	3167a
F^-	3183	—		Pr	3142a	—		Yb	3166a	—
Fe	3126a	1079b		Pt	3140	3140		Zn	3168a	3168a
Ga	3119a	—		Rb	3145a	—		Zr	3169	3169
Gd	3118a	—		Re	3143	—				
Ge	3120a	—		Rh	3144	3144				