

## Multi-Element Aqueous CRM

### ICH/USP Oral Target Elements Standard B

Matrix: 2% HNO<sub>3</sub>

Product #: VHG-ICH-USP-TELB-100

Lot #:1023164-1

Element	Certified Concentration & Uncertainty	Element	Certified Concentration & Uncertainty	Element	Certified Concentration & Uncertainty
Ag	150.0 ± 0.8 µg/mL	Ni	200.0 ± 1.0 µg/mL	Tl	8.00 ± 0.04 µg/mL
Co	50.10 ± 0.25 µg/mL	Se	150.0 ± 0.8 µg/mL	V	99.99 ± 0.50 µg/mL

**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:** VHG CRMs are manufactured and certified under a quality management system that is accredited to **ISO 9001**, **ISO Guide 34** 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 the NIST SRMs listed below. This solution was stabilized using high purity nitric acid (HNO<sub>3</sub>) and diluted with filtered (0.22µm), 18 M-ohm deionized water. The balances used in the preparation of VHG CRMs are calibrated regularly with traceability to NIST. All volumetric dilutions are performed in Class A calibrated glassware. The certified concentrations were determined by VHG Labs based upon gravimetric procedures. Secondary verification of the certified concentrations was performed by VHG Labs using ICP-OES that was calibrated and/or referenced against **NIST SRMs: 3151, 3113, 3136, 3149, 3158 and 3165**. 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: 1.00 g/mL

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

#### Trace Concentrations (µg/L)

Ag	MAJOR	Co	MAJOR	Ge	<0.5	Lu	<0.2	P	<100	Sb	4	Te	<1
Al	<2	Cs	<0.5	Hf	<0.2	Mg	<5	Pb	<1	Sc	<5	Ti	<2
As	3	Cr	10	Hg	0.7	Mn	<1	Pd	<0.5	Se	MAJOR	Tl	MAJOR
Au	<0.5	Cu	<1	Ho	<0.2	Mo	3	Pr	<0.2	Si	<100	Tm	<0.2
B	<5	Dy	<0.2	In	nd	Na	<25	Pt	<0.5	Sm	<0.2	V	MAJOR
Ba	<1	Er	<0.2	Ir	<0.2	Nb	<0.5	Rb	<0.5	Sn	<0.5	W	<0.5
Bi	0.5	Eu	<0.2	K	<25	Nd	<0.2	Re	<0.2	Sr	<1	Y	<0.5
Ca	<25	Fe	<10	La	<0.5	Ni	MAJOR	Rh	<0.5	Ta	<0.5	Yb	4
Cd	<0.5	Ga	<0.5	Li	<2	Os	<0.5	Ru	<0.5	Tb	<0.5	Zn	<2
Ce	<0.2	Gd	<0.2										

**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) use a minimum sub-sample size of 500µL, (4) make dilutions using calibrated balances or certified class A volumetric flasks and pipettes, (5) dilute with the same matrix as the original CRM or other chemically appropriate matrix, 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, immerse or expose the bottle or contents to direct sunlight.

**Period of Validity:** VHG 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.

VHG Labs, Inc.



Chuck Goudreau, Certifying Officer

See Exp. date on container  
Certification Date

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



**Hazardous Information:** Refer to the Material Safety Data Sheet (MSDS), which can be obtained at [www.vhqlabs.com](http://www.vhqlabs.com).

**Homogeneity:** This solution was determined to be homogeneous by procedures consistent with the requirements of ISO Guide 34 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.

**Further Information:** Please contact VHG Labs for further information about this CRM.

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

- ISO 9001 – Quality Management Systems – Requirements (Registrar: United Registrar Services, LLC)
- ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories
- ISO Guide 34 – General Requirements for the Competence of Reference Material Producers
  - ISO Guide 34 references additional requirements specified in ISO Guide 31 and ISO Guide 35.