Reference Material Certificate

Product Type:	USP-EP System Suitability/Verification/Standard Solution
Catalogue Number:	A-2221-040
	Rs 0.500mg/L C from USP Sucrose
Lot Number:	A-1692602-25
Certified Value:	0.500mg/L C ± 0.018mg/L C
Expanded Uncertainty:	U= ± 3.5%
Reference Value:	N/A
Source Material:	USP Sucrose R04312
Container:	40mL Borosilicate Glass Vial
Storage/Refrigeration:	Store in original container at 5 ± 4°C
Preservative:	N/A
Additional Information:	Please refer to SDS.
Certificate Issue Date:	02 Jul 2026 (Issue 2)
Expiry Date:	21 Sep 2026
Certifying Officer:	Stephanie Thornhill Quality Manager

Intended Use: This Certified Reference Material (CRM) is intended for USP/EP TOC System Suitability Testing, to calculate limit response and response efficiency in accordance with USP Chapter 643/EP Chapter 2.2.44. This CRM is manufactured using a starting material sourced from USP. USP do not operate to ISO 17034, and no uncertainty is assigned for the starting material. We therefore do not recommend the use of this material for calibration purposes. This CRM may be used to verify Total Carbon (TC = TIC + TOC) or, for analysers that compensate for Inorganic Carbon (IC), to verify Total Organic Carbon (TOC = TC – IC). The expanded uncertainty value (*U*) applies to both certified parameters.

Certified Value: CRMs are gravimetrically manufactured to **ISO 17034** [4] and verified to **ISO/IEC 17025** [3]. The Certified Value is the manufactured concentration. System Suitability Standards consist of the source material mixed with ultrapure, filtered, deionised water, with an initial TOC no greater than 0.040mg/L C and conductivity no greater than 1.0µS/cm at the point of production.

Metrological Traceability: All balances and check weights used are calibrated by a UKAS ISO/IEC 17025 Calibration Laboratory, providing traceability of measurement to the SI and/or to units of measurement realised at the National Physical Laboratory. Instrumentation used for analytical verification of this CRM is calibrated using standards traceable to Standard Reference Materials certified by the National Institute of Standards and Technology (NIST).

Measurement Method: Altus Science use a documented in-house method comprising UV persulphate oxidation followed by CO_2 detection, using membrane-based conductivity. Analytical verification of this product meets the acceptance criteria set by Altus Science.

Instructions for Use: CRMs should be kept in the original shipping container and stored in accordance with the storage/refrigeration instructions upon receipt. Prior to use, CRMs should be removed from storage, allowed to stabilise to ambient temperature and inverted three times. The single use container should remain tightly closed prior to use. Avoid contaminating open containers.

Period of Validity: Certified values are monitored, and purchasers will be notified of any significant changes resulting in recertification or withdrawal of this CRM during the period of validity. Altus Science CRMs are intended for single use only. The fitness for purpose of the material cannot be guaranteed after single use or beyond the expiry date shown above.

Accreditation: Altus Science (Laboratory ID: 8020) is accredited by the United Kingdom Accreditation Service (UKAS) as a Reference Material Producer to ISO 17034:2016, and to ISO 17025:2017 as a Testing Laboratory.

Contents of Certificates and Labels comply with the requirements of ISO 33401:2024 [5].

UKAS REFERENCE MATERIALS 8020

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Homogeneity Assessment: Homogeneity was assessed in accordance with ISO 33405:2024 [1]. Completed units were sampled using a random sampling protocol. The results of chemical analysis were then compared by Single Factor Analysis of Variance (ANOVA). Uncertainty due to the degree of homogeneity was derived using ANOVA (Homogeneity Uncertainty Contribution = $\sqrt{u^2}_{\text{Homogeneity}}$). Heterogeneity was not detected under the conditions of the ANOVA.

Expanded Uncertainty U_{CRM}: Uncertainty values in this document are expressed as Expanded Uncertainty. The reported Expanded Uncertainty is based on the combined uncertainty multiplied by a coverage factor, k= 2, providing a confidence level of 95%. The components of combined standard uncertainty include uncertainties due to characterisation, homogeneity, long term stability (storage), and short term stability (transport) as appropriate. The Expanded Uncertainty applies to the product as supplied [1, 2].

$$U_{CRM} = \sqrt{\boldsymbol{u}^2_{\text{Characterisation}} + \boldsymbol{u}^2_{\text{Homogeneity}} + \boldsymbol{u}^2_{\text{Stability}}}$$

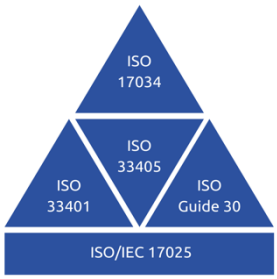
u Characterisation is the uncertainty in accordance with ISO/IEC 17025 which includes contributions from the primary reference material, temperature and the measuring system.

u Homogeneity is the between-bottle variation in accordance with ISO 17034. Assessment of homogeneity is performed by analysis of a representative number of randomly sampled units.

u Stability is the uncertainty obtained from short-term and long-term stability in accordance with ISO 17034. Stability studies are the basis for quantification of the expiry date of this Reference Material for the unopened container.

References:
1) ISO 33405:2024(E), Reference Materials – Approaches for characterization and assessment of homogeneity and stability.
2) ISO/IEC Guide 98-3:2008, Uncertainty of Measurement –Part 3: Guide to the Expression of Uncertainty in Measurement (GUM:1995).
3) ISO/IEC 17025:2017(E), General Requirements for the Competence of Testing and Calibration Laboratories.
4) ISO 17034:2016(E), General Requirements for the Competence of Reference Material Producers.
5) ISO 33401:2024(E), Reference Materials - Contents of Certificates, Labels and Accompanying Documentation.

Further Information: Additional Reference Material Certificates, Safety Data Sheets and information on the full range of Altus Science products can be found at **www.altusscience.com** or email **info@altusscience.com**.



ISO 17034: Accreditation as a Reference Material Producer
ISO 33405: Approaches for characterisation and assessment of homogeneity and stability
ISO 33401: Describes the contents of the reference material certificate and accompanying documentation
ISO Guide 30: Confirms that standards are characterised according to CRM definition
ISO/IEC 17025: Accreditation as a Testing Laboratory