

Product Type: USP-EP System Suitability/Verification or Standard Solution

Catalogue Number: A-4042-125

0.500mg/L C from USP Sucrose (Rs)

Lot Number : A-2511502-37
 Certified Value : 0.500mg/L C \pm 0.033mg/L C
 Expanded Uncertainty: $U = \pm 6.51\%$
 Reference Value: N/A
 Source Material : USP Sucrose Lot IO1179

Certificate Issue Date: 10 Sep 2015

Expiration Date: 08 Nov 2015

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. ^[1] Altus Science do not recommend the use of USP Sucrose for Calibration purposes. This CRM may be used to verify Total Carbon (TC = TIC + TOC), or for analysers that compensate for inorganic carbon (IC), the solution is also certified for TOC (TOC = TC – IC). The expanded uncertainty value (U) applies to both certified parameters.

Description: One unit of Altus Science TOC Calibration standard consists of a 125ml solution produced from ultrapure, filtered, deionised water with an initial total organic carbon (TOC) no greater than 0.100 mg/L carbon, and having a conductivity no greater than 0.058 μ S/cm (at point of production). These solutions are stored and shipped in scrupulously cleaned 125ml HDPE vials.

Instructions for Use: These CRMs should be stored in the original shipping container and refrigerated at 5 ± 4 °C upon receipt. Bottles should remain tightly closed between uses. Avoid contaminating open containers. The certified values and stated uncertainties will be valid through the date listed on the bottle.

Period of Validity: The certified values are monitored and purchasers will be notified of any significant changes resulting in recertification or withdrawal of this certified reference material during the period of validity of this certificate. The 125ml ready to use standards are intended for single use only. The validity period is invalid once opened or used.

Homogeneity Assessment: Homogeneity was assessed in accordance with ISO Guide 35 ^[2]. Completed units were sampled using a random sampling protocol. The results of chemical analysis were then compared by Single Factor Analysis of Variance (ANOVA). The uncertainty due to homogeneity was derived from the ANOVA (Homogeneity Uncertainty Contribution = $\sqrt{u_{bb}^2}$). Heterogeneity was not detected under the conditions of the ANOVA.

Uncertainty Statement: Uncertainty values in this document are expressed as Expanded Uncertainty. The reported Expanded Uncertainty is based on a standard uncertainty multiplied by a coverage factor $k=2$ providing a confidence level of 95%. The components of combined standard uncertainty include the uncertainties due to characterisation, homogeneity, long term stability, and short term stability (transport) as appropriate. Uncertainty is calculated using TOC or TIC measurement.

The Expanded Uncertainty applies to the product as supplied ^[2,3].

Traceability: The CRMs are manufactured from the USP Sucrose reference standard sources shown above. This results in direct **Metrological Traceability** to United States Pharmacopeia (USP) reference materials ^[1].

Certified Value: Is determined under **double-accreditation** in accordance with ISO/IEC 17025 ^[4] and also ISO Guide 34 ^[5]. The Certified Value is the actual "made-to" concentration confirmed by Altus Science. TOC analytical verification and acceptance criteria are set for quality acceptance of this product.

Method of Preparation: This material was prepared and certified by Altus Science, the assigned value is determined gravimetrically. The TOC CRM consist of ultrapure, filtered, deionised water with an initial TOC no greater than 0.100 mg/L C and having a conductivity no greater than 0.058 μ S/cm at point of production together with USP Sucrose. This solution is stabilised.

Quality Standard Documentation: Altus Science are Accredited by the United Kingdom Accreditation Service (UKAS) to ISO 17025:2005 as a Testing Laboratory, and ISO Guide 34:2009 for CRM manufacture. Contents of Certificates and Labels comply with the requirements of ISO Guide 31:2000 ^[6].

Certifying Officer:  Mr. Graham Roscoe

References:

- 1) US Pharmacopeia 37-NF 31, General Chapter USP Total Organic Carbon <643>, (USP Convention, USA, 2012).
- 2) ISO Guide 35:2006(E), Reference materials-General and Statistical Principles.
- 3) ISO/IEC Guide 98-3:2008, Uncertainty of Measurement – Part 3: Guide to the Expression of Uncertainty in Measurement (GUM:1995).
- 4) ISO/IEC 17025:2005(E), General Requirements for the Competence of Testing and Calibration Laboratories.
- 5) ISO Guide 34:2009(E), General Requirements for Competence of Reference Material Producers.
- 6) ISO Guide 31:2000(E), Reference Materials - Contents of Certificates and Labels.

This certificate is issued in accordance with the laboratory accreditation requirements to ISO 17025:2005 of the United Kingdom Accreditation Service (UKAS). UKAS is one of the signatories to the Multilateral Agreement of the European co-operation for Accreditation (EA) as well as the International Laboratory Accreditation (ILAC) Arrangement for the mutual recognition of calibration certificates issued by accredited laboratories. This certificate may NOT be reproduced other than in full, except with the written approval of Altus Science Limited.

Altus Science Limited
 Sci-Tech Daresbury
 Vanguard House, Daresbury
 Cheshire, WA4 4AB, United Kingdom
 P: +44(0) 1925 606528
 E: info@altusscience.com



8020



8020