

Product Type: USP-EP System Suitability/Verification/Standard Solution
Catalogue Number: A-3403-030
Rss 0.500mg/L C from USP 1,4-Benzoquinone
Lot Number: A-2172503-32
Certified Value: 0.500mg/L C $\pm$ 0.014mg/L C
Expanded Uncertainty: U = $\pm$ 2.7%
Reference Value: N/A
Source Material: USP 1,4-Benzoquinone R15690
Container: 30mL PPCO Vial
Storage/Refrigeration: Store in original container at $5 \pm 4^{\circ}\text{C}$
Preservative: N/A
Additional Information: Please refer to SDS.

Certificate Issue Date: 06 Aug 2025

Expiry Date: 08 Nov 2025

Certifying Officer: Sharon McGahan
Quality Technician



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 1.0 $\mu\text{S}/\text{cm}$ at the point of production.

Metrological Traceability: All balances and check weights used are calibrated by a UKAS ISO/IEC 1702

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].

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

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.