

Certification Report – Certified Reference Material

Certipur® Conductivity Standards

Manufacturer:

Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany, Tel. +49(0)6151 720

Accreditation:

Merck KGaA, Darmstadt, Germany is accredited by the German accreditation authority as registered reference material producer (D-RM-15185-01-00) in accordance with **ISO 17034**.

Introduction:

This certification report contains additional information about certified values and uncertainties, homogeneity, stability, traceability and other relevant details of Certipur® conductivity standards.

The scope of the ISO 17034 accreditation is documented in the annex to the accreditation certificate D-RM-15185-01-00. The conductivity standards are produced, characterized and certified by the legal entity Merck KGaA, Darmstadt, Germany.

Preparation and packaging of CRMs:

Certipur® conductivity standards are prepared gravimetrically from high purity potassium chloride (product no. 1.04936) and high purity water (product no. 1.16754). All balances are regularly calibrated with analytical weight sets traceable to primary weights by PTB. After preparation the solutions are allowed to equilibrate with atmospheric carbon dioxide. The certified values are based on this equilibrium condition.

Certipur® conductivity standards are delivered in 500 ml high-density PE bottles. The label on the products is in accordance to ISO Guide 31 and covers ordering number, article description, lot number, expiry date and safety data information. Packaging material is subject to comprehensive stability studies according to ISO Guide 35.

Homogeneity:

Homogeneity studies were conducted in accordance to ISO Guide 35.

A representative number of samples packaged in their final form was chosen systematically (stratified over the whole batch) for assessment of the between bottle homogeneity. Measurements have been carried out according to DIN EN ISO/IEC 17025. Results from multiple samples of the chosen bottles were evaluated.

Typical homogeneity contributions to uncertainty u_{hom} are in the range of 0.1%.

Stability:

Stability studies were conducted in accordance to ISO Guide 35.

Stability comprises long- term stability, which is associated with the storage behavior of the CRMs under recommended storage conditions as well as short-term stability that takes any extra effects due to transport of the products into account (quantification of transport effects that result from temperature variations during shipment).



Long-term stability:

Long-term stability of the products was evaluated in close collaboration with Physikalisch Technische Bundesanstalt (PTB), Germany using the classical experimental layout. Samples were stored at the recommended storage conditions before measurement. Conductivity measurements were conducted by PTB according to DIN EN ISO/IEC 17025. Results were evaluated using a linear regression model and the slope as well as the uncertainty of the slope is included into the uncertainty budget as long-term stability contribution u_{lts} .

Typical long-term stability contributions to uncertainty u_{lts} are in the range of 0.5%.

Short-term (transportation) stability:

Short-term stability was evaluated using the classical experimental layout. Samples were stored at elevated temperatures that may arise during shipment of the products before measurement. Results were evaluated using a linear regression model and as the slope did not significantly differ from zero the uncertainty of the slope is included into the uncertainty budget as short-term stability contribution u_{sts} .

Typical short-term stability contributions to uncertainty u_{sts} are in the range of 0.1%.

Stability monitoring:

Merck KGaA, Darmstadt, Germany will monitor all Certipur® conductivity standards over the period of their certification (until expiry date). If substantive technical changes occur that affect the validity of certification, the customer will be notified.

Characterisation:

Characterisation of Certipur® conductivity standards is carried out by the accredited quality control (QC) laboratory at Merck KGaA, Darmstadt, Germany according to DIN EN ISO / IEC 17025 by conductivity measurements with a 4-pole measuring cell (WTW Tetracon 96).

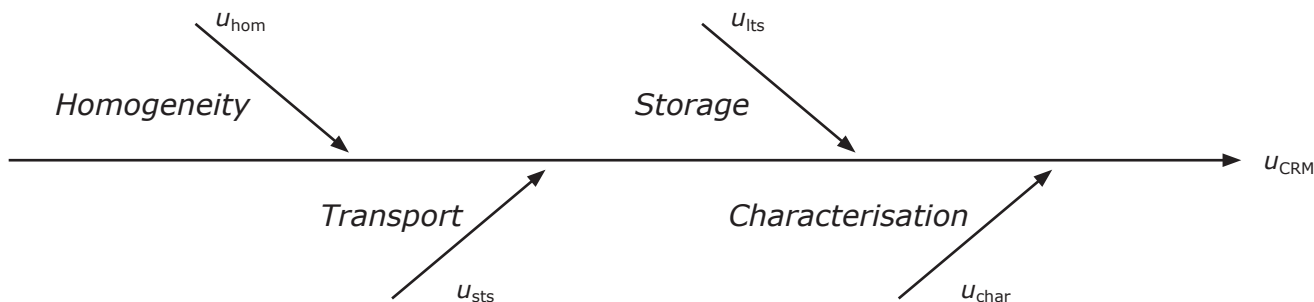
Typical characterisation contributions to uncertainty u_{char} are in the range of 0.5%.

Traceability:

All certified values of Certipur® conductivity standards are traceable to corresponding primary conductivity standards (Merck KGaA, Darmstadt, Germany, characterized by PTB) via an unbroken chain of calibrations and additionally measured against corresponding NIST Standard Reference Materials (SRM).

Uncertainty evaluation:

The expanded uncertainty U_{CRM} reported with the certified values is calculated in accordance to GUM and EA-4/02, with $k=2$ as the coverage factor for a 95% coverage probability. Uncertainty contributions to the certified expanded uncertainty are illustrated by the following cause-and-effect-diagram (Ishikawa-Diagram):



The expanded uncertainty u_{CRM} is obtained from the standard uncertainties of characterisation, homogeneity and stability:

$$U_{\text{CRM}} = k \cdot u_{\text{CRM}}$$

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

$$u^2_{\text{Stability}} = u^2_{\text{sts}} + u^2_{\text{Its}}$$

Quality management system:

Certipur® conductivity standards have been prepared and certified under an ISO 9001 quality management system in accordance to

ISO 17034: General requirements for the competence of reference material producers

ISO Guide 35: Reference materials – General and statistical principles for certification

ISO Guide 31: Reference materials – Contents of certificates and labels

Eurachem / CITAC Guide: Quantifying uncertainty in analytical measurement

Guide to the Expression of Uncertainty in measurement (GUM)

DIN EN ISO / IEC 17025: General requirements for the competence of testing and calibration laboratories

