



Certificate of Analysis

Aquastar™ Certified Reference Material

Producer:	Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany.
Accreditation:	Merck KGaA, Darmstadt, Germany is accredited as calibration laboratory according to DIN EN ISO/IEC 17025 .
Description of CRM:	Water Standard 1% certified reference material for volumetric and coulometric Karl Fischer Titration
Ord. No.:	1.88052.0010
Lot No.:	HC87402152
Composition:	1-Methoxy-2-propanol
Certified value and uncertainty:	1.007 % ± 0.010 % (10.07 mg/g ± 0.10 mg/g) water content with expanded uncertainty U_{CRM}
Traceability:	The certified value of this reference material is directly traceable to SI-Unit (kg) and verified by NIST SRM 2890. <i>NIST: National Institute of Standards and Technology, Gaithersburg, USA.</i>
Method of Analysis:	The water content is determined by coulometric Karl Fischer Titration on 10 ampoules according to ISO 760.
Storage:	+15°C to +25°C tightly closed in the original container
Application and correct use:	This certified reference material is intended for use as a standard for checking the accuracy of Karl Fischer equipment according to ISO 9001 chapter 7.1.5 "Monitoring and measuring resources" of coulometric Karl Fischer Titrators. It can also be used to standardise the titrant according to European Pharmacopeia (Ph.Eur.) chapter 2.5.12 "Water Semi-Micro Determination" and according to the United States Pharmacopeia <921> "Water Determination". For the daily verification we recommend to accept a deviation of ± 0.015 % (± 0.15 mg/g) from the certified value.
Date of release:	2018/12/04
Expiry date:	2023/11/30

A. Yildirim

Dipl.-Ing. Ayfer Yildirim
(Laboratory manager)

Expanded uncertainty U_{CRM} :

The expanded uncertainty U_{CRM} is calculated as $U_{\text{CRM}} = k \cdot u_{\text{CRM}}$, where $k=2$ is the coverage factor for a 95 % coverage probability and u_{CRM} is the combined standard uncertainty in accordance to ISO Guide 34.

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

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

$u_{\text{Characterisation}}$ is the uncertainty in accordance with DIN EN ISO/IEC 17025 which includes the contributions of the primary reference material and the measuring system.

$u_{\text{characterisation}}$ in the certified value is calculated in accordance to EA-4/02 and GUM.

$U_{\text{Characterisation}}$ is 0.0035 % (0.035 mg/g) (calculated as $U_{\text{Characterisation}} = k \cdot u_{\text{Characterisation}}$ with $k=2$)

$u_{\text{Homogeneity}}$ is the between-bottle variation in accordance with ISO Guide 34. The assessment of homogeneity is performed by analysis of a representative number of systematically chosen sample units.

$u_{\text{Stability}}$ is the uncertainty obtained from short-term and long-term stability in accordance with ISO Guide 34. The stability studies are the basis for the quantification of the minimum shelf life of this water standard for the unopened ampoule.

Instructions for correct use

1. Open ampoule at the marked point of break.
2. Rinse a plastic syringe 1-2 times with about 1 ml of standard solution.
3. Draw up the entire ampoule content into the rinsed syringe.
4. Weigh the filled syringe before injection.
5. Inject about 0.5-1 ml of standard solution into the titration cell and start the titration.
6. Determine the exact standard solution weight by reweighing the syringe after injection.
7. Repeat the determination. The content of one ampoule is sufficient for 3 determinations. Open the ampoule only directly prior to starting of measurement. Solvent in the opened ampoule can absorb moisture and distort results.