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EM1.88050.0010

Certificate of Analysis – Reference Material

Aquastar® Water Standard 0.01%

Producer: Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany
Product no.: 1.88050.0010
Lot no.: HC44001750
Description of RM: Water Standard 0.01%
Reference Material for Karl Fischer titration, 1g ≙ 0.1 mg H_2O, Aquastar®
Expiry date: 2025/12/31
Storage: +15°C to +25°C tightly closed in the original container
Composition: Xylene (mixture of isomers)

Analyte	Measured value as mass fraction	Associated uncertainty, $U=k \cdot u$ ($k=2$) as mass fraction
Water	**0.0097%**	**±0.0010%**
	0.097 mg/g	**±0.010 mg/g**

Metrological traceability: Directly traceable to SI Unit (kg) and verified by NIST SRM 2890.

Measurement method: The water content is determined by coulometric Karl Fischer Titration (n ≥ 10) according to ISO 760.

Intended use: Reference material 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 and checking measuring results according to European Pharmacopeia (Ph.Eur.) chapter 2.5.32 "Water Micro Determination".

Instructions for handling and correct use: The RM should be stored in the original (unopened) ampoule at room temperature (15-25°C). Open the ampoule only directly before measurement. Do not store opened ampoules. Solvent in the opened ampoule can absorb moisture and distort results. For the daily verification we recommend to accept a deviation of ± 0.0015% (± 0.015mg/g) from the measured value. See Details for correct use on page 2.

Accreditation: Merck KGaA, Darmstadt, Germany is accredited as calibration laboratory according to DIN EN ISO/IEC 17025.

Certificate issue date: 2024/07/04

RM released by Approving Officer
or delegate of Quality Control

A. Yildirim

Dipl.-Ing. Ayfer Yildirim
Responsible Laboratory Manager

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Health and safety information: Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

Details on correct use:

1. Open the 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 1-2 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.

Certification process details:

Aquastar® Water Standard 0.01% is prepared gravimetrically from high purity water and xylene. All balances are regularly calibrated with analytical weight sets traceable to primary weights by PTB (Physikalisch Technische Bundesanstalt).

Characterisation of Aquastar® Water Standard 0.01% is carried out by the accredited quality control (QC) laboratory at Merck KGaA, Darmstadt, Germany according to DIN EN ISO / IEC 17025. The water content of Aquastar® Water Standard 0.01% is measured by means of direct coulometric Karl Fischer titration (according to ISO 760).

Associated uncertainty:

The associated uncertainty U_{CRM} reported with the measured values is calculated as combined expanded uncertainty $U_{CRM}=k \cdot u_{CRM}$ in accordance with GUM and EA-4/02, with $k=2$ as the coverage factor for a 95% coverage probability.

The combined uncertainty u_{CRM} is derived from combination of the squared uncertainty contributions:

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

$u_{characterisation}$: is the uncertainty in accordance with DIN EN ISO/IEC 17025 which includes e.g. contributions of the primary reference material and the measuring system. The characterisation measurements have been conducted by our DAkkS accredited calibration laboratory.

$u_{Characterisation}$ in the measured value is calculated in accordance to EA-4/02 and GUM.

$U_{Characterisation}$ is 0.0004% (0.004 mg/g) (calculated as $U_{Characterisation} = k \cdot u_{Characterisation}$ with $k=2$)

$u_{homogeneity}$: is the between-bottle variation in accordance with ISO 17034. The assessment of homogeneity is performed by analysis of a representative number of systematically chosen sample units.

$u_{stability}$: is the uncertainty obtained from short-term and long-term stability in accordance with ISO 17034. The stability studies are the basis for the quantification of the expiry date of this water standard for the unopened ampoule.

For more detailed information please read the certification report on our website.

Certificate of analysis revision history:

Certificate version	Date	Reason for version
01	2024/07/04	Initial version