

Certificate of Analysis – Certified Reference Material

Aquastar® Sodium tartrate dihydrate



Product no.: 1.06664.0100
Lot no.: FN1463164
Description of CRM: Sodium tartrate dihydrate
 Certified Reference Material for Karl Fischer titration, 15.66%, Aquastar®
Expiry date: 2022/05/31
Storage: +15°C to +25°C tightly closed in the original container
Composition: Sodium tartrate dihydrate

Analyte	Certified value as mass fraction	Associated uncertainty, $U=k \cdot u$ ($k=2$) as mass fraction
Water	15.68 %	±0.05 %
	156.8 mg/g	±0.5 mg/g

Metrological traceability: Directly traceable to SI Unit (kg).
Measurement method: The water content is determined by loss on drying at 150°C.
Intended use: This certified reference material is intended for use as a standard for standardisation of the volumetric Karl Fischer titrants. 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 United States Pharmacopeia <921> "Water Determination" as well as according to ISO 760.
Instructions for handling and correct use: The CRM should be stored in the original (unopened) bottle at room temperature (15-25°C). See Details for correct use on page 2.
Accreditation: Merck KGaA, Darmstadt, Germany is accredited by the German accreditation authority DAkkS as registered reference material producer D-RM-15185-01-00 in accordance with ISO 17034 and registered calibration laboratory D-K-15185-01-00 according to DIN EN ISO/IEC 17025.
Certificate issue date: 2020/07/07

CRM released by Approving Officer
or delegate LS-OII-QS3



ISO 17034



ISO/IEC 17025



A. Yildirim

Dipl.-Ing. Ayfer Yildirim
Responsible Manager of LS-OII-QS3
(Calibration Laboratory K-15185-01)



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:

- Weigh in 50 – 150mg into a weighing boat.
- Weigh the filled weighing boat before addition.
- Add the solid standard substance into the titration cell and start the titration.
- Determine the exact amount of standard by reweighing the weighing boat after addition.
- For complete dissolution a stirring time of 180s is recommended.

Certification process details:

This Aquastar® Karl Fischer standard is prepared gravimetrically from high purity salts.

Characterisation of Aquastar® Karl Fischer standard Sodium tartrate dihydrate is carried out by the accredited quality control (QC) laboratory at Merck KGaA, Darmstadt, Germany according to DIN EN ISO / IEC 17025 by measuring the water content by loss on drying.

Homogeneity and stability studies are performed with the material according to the requirements of ISO 17034 and ISO Guide 35.

Associated uncertainty:

The associated uncertainty U_{CRM} reported with the certified 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:

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

$u_{\text{characterisation}}$:

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 0.01% (0.1 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 17034. 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 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	2020/07/07	Initial version

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The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the US and Canada.

