Specification – Certified Reference Material

Aquastar® Lactose Standard 5%

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**.

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DAkkS
Deutsche
Akkreditierungsstelle
D-RM-15185-01-00

Producer:	Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany
Product no.:	1.12939.0010
Description of CRM:	Lactose Standard 5%
	Certified Reference Material for Karl Fischer, Aquastar®
Expiry date:	2 years
Storage:	+15°C to +25°C tightly closed in the original container
Composition:	Lactose monohydrate

Analyte	Specification as mass fraction	Associated uncertainty, $U=k \cdot u$ ($k=2$) as mass fraction
Water	**5.00 – 5.20%**	**±0.05%**
	50.0 – 52.0 mg/g	**±0.5 mg/g**

Metrological traceability:	Directly traceable to SI Unit (kg).
Measurement method:	The water content is determined by coulometric Karl Fischer oven method at 150°C and an extraction time of 300s (n ≥ 10).
Intended use:	Certified reference material for checking the accuracy of coulometric and volumetric water determinations with and without using a Karl Fischer oven and according to ISO 760.

Certification process details:

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

Characterisation of Aquastar® Lactose Standard 5% 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 with coulometric Karl Fischer oven method.

Homogeneity and stability studies are performed with the material according to the requirements of ISO 17034 and ISO 33405.

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:

$$u_{CRM} = \sqrt{u^2_{characterisation} + u^2_{homogeneity} + u^2_{stability}}$$

$u_{characterisation}$:	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.
	$u_{characterisation}$ in the certified value is calculated in accordance to EA-4/02 and GUM.
	$U_{characterisation}$ is 0.025% (0.25 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 bottle.

Detailed information is provided by the certificates and the certification report on our website.

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