Specification – Certified Reference Material

Volumetric Standards

Certified Reference Material for standardization of volumetric solutions

Accreditation:

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

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**.

Producer: Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany
Description of CRM: Volumetric Standards
Certified Reference Materials for standardization of volumetric solutions
Storage: +15°C to +25°C tightly closed in the original container

Analyte	Expiry date	Specification as mass fraction	Associated uncertainty*, $U=k\cdot u$ ($k=2$)
Potassium hydrogen phthalate	5 years	≥ 99.80%	0.10%
Benzoic acid	5 years	≥ 99.80%	0.10%
Iron(II)ethylenediammonium sulfate	3 years	≥ 99.50%	0.35%
Potassium dichromate	5 years	≥ 99.90%	0.10%
Potassium iodate	5 years	≥ 99.70%	0.10%
Sodium carbonate	5 years	≥ 99.80%	0.10%
Sodium chloride	5 years	≥ 99.85%	0.10%
di-Sodium oxalate	5 years	≥ 99.70%	0.10%
Tris(hydroxymethyl)amino-methane	5 years	≥ 99.80%	0.10%
Zinc	5 years	≥ 99.90%	0.10%
Calcium carbonate	5 years	≥ 99.80%	0.10%

* The uncertainty can vary depending on the primary reference material.

Metrological traceability: Directly traceable to the corresponding / suitable primary standard NIST SRM
NIST: National Institute of Standards and Technology, Gaithersburg, USA

Measurement method: The certified mass fraction was determined by potentiometric titration.

Intended use: These volumetric standards are intended for standardisation of volumetric solutions in accordance / relation to the chapter reagents of the Pharmacopoeia (Ph. Eur., USP where applicable).

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 the contributions of the primary reference material and the measuring system. The characterisation measurements have been conducted by our DAkkS accredited calibration laboratory.

$u_{homogeneity}$: 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 reference material for the unopened bottle.

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

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