

## Specification – Certified Reference Material

### Volumetric Standards

Certified Reference Material for standardization of volumetric solutions

#### Accreditation:



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*,<br>$U=k \cdot u$ ( $k=2$ ) |
|------------------------------------|-------------|--------------------------------|-----------------------------------------------------|
| 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:

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

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

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

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

