

# Specification



## Certipur® Certified Reference Material

**Producer:** Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany.

**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 Guide 34** and registered calibration laboratory D-K-15185-01-00 according to **DIN EN ISO/IEC 17025**.



**Description of CRM:** **Potassium hydrogen phthalate certified secondary standard reference material**  
**pH(S)= 4.00<sub>5</sub> (25°C)**  
certified reference material for pH measurement

**Ord. No.:** 1.01965.0025

**Lot No.:** sample

**Composition:** Potassium hydrogen phthalate  
Formulation in compliance with DIN 19266, IUPAC, NIST, European Pharmacopeia (Ph. Eur.) and United States Pharmacopeia (USP)

**Certified value and uncertainty:**

T [°C]	certified pH ± $U_{CRM}$ (KHC <sub>8</sub> H <sub>4</sub> O <sub>4</sub> 0.05 mol/kg)
5.0	3.993 - 4.013 ± 0.009
10.0	3.988 - 4.008 ± 0.009
15.0	3.988 - 4.008 ± 0.009
20.0	3.992 - 4.012 ± 0.009
<b>25.0</b>	<b>3.997 - 4.017 ± 0.009</b>
30.0	4.004 - 4.024 ± 0.009
37.0	4.017 - 4.037 ± 0.009
40.0	4.024 - 4.044 ± 0.010
45.0	4.037 - 4.057 ± 0.010
50.0	4.050 - 4.070 ± 0.010

pH value with expanded uncertainty  $U_{CRM}$

**Method of Analysis:** The pH value is directly measured by differential potentiometry with the aid of two platinum hydrogen electrodes “quasi without transference” according to IUPAC<sup>1</sup> recommendations against solutions prepared from primary reference materials characterised by PTB and NIST.

**Expiry date:** 4 years



**(Laboratory manager)**

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**Traceability:** This certified secondary standard reference material is directly traceable to primary certified reference material potassium hydrogen phthalate characterised by PTB and NIST.

NIST xxx

PTB xxx

PTB: Physikalisch Technische Bundesanstalt, Braunschweig, Germany

NIST: National Institute of Standards and Technology, Gaithersburg, USA.

**Preparation:** The formulation is compliant to DIN 19266, IUPAC<sup>1</sup>, NIST<sup>2</sup>, Ph. Eur. chapter 2.2.3 and USP chapter <791>.

**Storage:** +15°C to +25°C tightly closed in the original container

**Application and correct use:** **Preparation of potassium hydrogen phthalate 0.05 mol/kg (pH(S)=4.00<sub>5</sub>):**

Dry potassium hydrogen phthalate for 2 hours at 110 – 130°C before weighing. Dissolve 10.21 g Potassium hydrogen phthalate in 800 ml of water and make up to 1000 ml at 25°C. This solution is stable for approximately 6 weeks. Do not use any solution that shows signs of fungal contamination within this period.

Through within-bottle homogeneity a minimum sample volume of 30ml was determined. The weigh-in quantity depends on the buffer substance and has to be calculated.

This reference material is intended for use as a calibration standard for pH instruments and pH electrodes. The pH value strongly depends on the temperature. Therefore it is necessary to keep the temperature constant during the measurement. Details concerning the nature of any hazard and appropriate precautions are provided in the material safety data sheet.

**Expanded uncertainty  $U_{CRM}$ :** The expanded uncertainty  $U_{CRM}$  is calculated as  $U_{CRM} = k \cdot u_{CRM}$ , where  $k = 2$  is the coverage factor for a 95% coverage probability and  $u_{CRM}$  is the combined standard uncertainty in accordance to ISO Guide 34.

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

The combined standard uncertainty  $u_{CRM}$  is obtained from the standard uncertainties of the characterisation, the homogeneity and the stability.

$u_{\text{Characterisation}}$  is the uncertainty in accordance to DIN EN ISO/IEC 17025 which includes the contributions of the primary reference material and the measuring system.

$u_{\text{Homogeneity}}$  is the between-bottle variation in accordance to ISO Guide 34. 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 to ISO Guide 34. The stability studies are the basis for the quantification of the minimum shelf life of this reference material for the unopened bottle.

For more detailed information please read the certification report on [www.merckmillipore.com](http://www.merckmillipore.com)

<sup>1</sup> R.P. Buck, S. Rondinini, A. K. Covington, F.G.K. Baucke, C. M. A. Brett, M. F. Camoes, M. J. T. Milton, T. Mussini, R. Naumann, K. W. Pratt, P. Spitzer, G. S. Wilson: **The Measurement of pH – Definition, Standards and Procedures (IUPAC Recommendations 2002)**, Pure Appl. Chem, Vol 74, No. 11, pp. 2169-2200, 2002

<sup>2</sup> Y. Ch. Wu, W. F. Koch, R. A. Durst: **Standardization of pH Measurements**, NBS Special Publication 260-53, 1988