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Certificate of Analysis – Certified Reference Material

Certipur® Potassium hydrogen phthalate

Ado 11/19

ISO 17034 · DIN EN ISO/IEC 17025
Accredited as CRM Producer and Calibration Laboratory

Product no.:	1.02400.0080
Lot no.:	192400D
Description of CRM:	Potassium hydrogen phthalate
Expiry date:	2024/05/31
Storage:	+15°C to +25°C tightly closed in the original container and protect from light and moisture
Composition:	Potassium hydrogen phthalate

Analyte	Certified value as mass fraction	Associated uncertainty, $U=k \cdot u$ ($k=2$) as mass fraction
Mass fraction	**99.92 %**	**±0.07 %**

Metrological traceability: Directly traceable to the suitable primary standard NIST SRM Potassium hydrogen phthalate 84L.

Measurement method: The certified mass fraction was determined by potentiometric titration with sodium hydroxide as titration solution. The certified value is based on a molecular mass M = 204.222 g/mol dried substance.

Intended use: This volumetric standard is intended for standardisation of volumetric solutions in accordance to the chapter reagents of the Pharmacopoeia (Ph. Eur., USP).

Instructions for handling and correct use: The volumetric standard Potassium hydrogen phthalate must be dried at 120 °C for 2 hours before use.
By within-unit homogeneity studies a minimum weigh-in quantity of 175 mg was determined.

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: 2019/07/04

DAkkS Deutsche Akkreditierungsstelle D-RM-15185-01-00 — ISO 17034

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DAkkS Deutsche Akkreditierungsstelle D-K-15185-01-00 — ISO/IEC 17025

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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.

Certification process details:

Certipur® Volumetric standards are prepared from high purity salts. Characterisation of Certipur® Volumetric standards 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 mass fraction by potentiometric titration.

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:

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

$u_{characterisation}$: is the uncertainty in accordance with DIN EN ISO/IEC 17025 which includes the contributions of the primary reference material and the measuring system.

$u_{homogeneity}$: 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 volumetric standard for the unopened bottle.

For more detailed information please read the certification report on our website.

Certificate of analysis revision history:

Certificate version	Date	Reason for version
01	2019/07/04	Initial version