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Certificate of Analysis

Certified Reference Material

This document is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO Guide 31 [1], ISO Guide 35[2], EA 4/02 and Eurachem / CITAC Guides[3]

Lot N: XXXXXX Barcode: XXXXXXXX Certification Date: XXXXXXXXXX

Description of the RM subject of calibration: Lactose standard 5%, solid water standard

Ref N: KFOVEN.10G.10G

Calibration method: CRM's calibration procedure (WQP 5.15.1.26)

Result from calibration (Certified value/Uncertainty): 5.014 +/- 0.026 % H_2O

** The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k = 2, which for a normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined in accordance with EA 4/02.*

Concept of Certification and traceability statement:

The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k = 2, which for a normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined in accordance with EA 4/02
Property of the result of a measurement whereby it can be related to stated references, usually national or international standards, trough an unbroken chain of comparisons all having stated uncertainties (ISO VIM [5])
The metrological traceability is assured through Karl Fisher coulometric titration and confirmed through gravimetric measurement. The method is tested against NIST SRM 2890.
The measured water content is traceable to Si-unit (kg)
. All analytical balances used for the preparation of the solution are calibrated yearly under an in-house procedure with class E1 and class E2 analytical weights, traceable to SI (DKD) and are checked daily.
Class A laboratory glassware is used.
The results from temperature measurement are traceable to SI. The thermometers used for solution's calibration are calibrated from an ISO 17025 accredited laboratory. The ambient conditions are controlled with a hygrometer calibrated from an ISO 17025 accredited laboratory.

Expiry date: XXXXXX

Intended use:

For Laboratory Use Only

This CRM is intended for:

I. Calibration by Karl Fisher coulometric/ volumetric titration
II. Karl Fischer oven method
III. Validation of analytical methods
IV. Preparation of "working reference samples"
V. Detection limit and linearity studies

This standard also meets the requirements of the European Pharmacopoeia on a "Standard solution for the micro-determination of water.

This statements are not intended to restrict the use for other purposes.

Instructions for the correct use of this reference material:
This certified reference material can be used directly.

Stability and storage:

This CRM is with a guaranteed stability until ±0.5% of the certified value within its shelf-life. Stability is guaranteed provided that the solution is kept in its original packaging, tightly closed under normal laboratory conditions. According to an in-house procedure the producer will monitor this CRM at appropriate intervals and the purchasers will be notified of any significant changes resulting in recertification or with withdrawal of the CRM during the state period of the validity of the certificate.

DOMINIQUE DUTSCHER SAS

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Hazardous situation:

The normal laboratory safety precautions should be observed when working with this RM. Further details for the handling of this RM are available as safety data sheet.

Level of homogeneity:

This solution was mixed according to an in-house procedure and is guaranteed to be homogeneous.
To ensure sufficient homogeneity of the sample prior to use thoroughly mix by inversion.

This certificate relates solely to the lot number given above.
All processes (including generating of this certificate) are completely controlled by the specialized Computer-Aided-Manufacturing (CAM) software.

This Certified Reference Material was produced under a quality management system that is:
- Registered to ISO 9001 Quality Management System (Lloyd's Register Quality Assurance Ltd Cert No 0039638)
- Accredited according to ISO/IEC 17025 – Testing (ANAB Cert No AT-1836)
- Accredited according to ISO 17034 - Reference Material Producer (ANAB Cert No AR-1835)

Names of certifying officers:
Laboratory: Galya Jeleva

Manager: Krassimira Taralova

[1] ISO Guide 31: Reference materials - Contents of certificates and labels
[2] ISO Guide 35: Reference materials - General and statistical principles for certification
[3] EURACHEM/CITAC Guide: Quantifying Uncertainty in Analytical Measurement
[4] EA 4/02: Expression of the Uncertainty of Measurement in Calibration
[5] ISO/IEC Guide 99: International Vocabulary of Metrology-Basic and general concepts and associated terms (VIM)
[6] ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
[7] ISO Guide 34: General Requirements for the Competence of Reference Material Producers

Signed by: Taralova, Chemical Production Manager

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