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Certificate of Analysis

CERTIFIED REFERENCE MATERIAL

Certified reference solution for osmometer calibration - 850 mOsm/kg H2O

Lot N: XXXXXX
Barcode: XXXXXXXX

Ref N: OSM0850.L06

Certification Date:XXXXXX

Certified Value* (mOsmol/kg)	**Uncertainty**** (mOsmol/kg)
850	+/- 3

** The certified value was obtained using Osmometer calibration acc. to in-house procedure WQP 5.15.1/35*
*** 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.*

Metrological traceability:

The metrological traceability is assured through calibration on Osmometer. The calibration curve is drawn using standard solutions prepared gravimetrically acc. to table 2.2.35.-1 from European Pharmacopoeia. All contributions in relation to the preparation of standard solutions are considered when evaluating the uncertainty.
This certified reference material is produced by dissolving high-purity Sodium Chloride in 18 MOhm deionized water (filtered through a 0.22 um filter).
The measurement results are traceable to SI. 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 DKD and are daily checked.
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

Storage Conditions: Store under normal laboratory conditions, at temperatures between 15° to 25°C

Intended use: For Laboratory Use Only

This CRM is intended for:
- Calibration of Osmometer.
- Validation of analytical methods
- Preparation of "working reference samples"
- Detection limit and linearity studies

This statement is 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.
Do not store the solution after opening the ampoule.

Stability and storage:

DUPLICATA SAS

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for France, Belgium and Switzerland:
e-mail: acsd2@wanadoo.fr; tel.:01 30 57 57 32 / fax: 01 30 57 57 33

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 stored, as written in the section: Storage 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.

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:

The material was tested for homogeneity by analyzing randomly selected samples according to an in-house procedure. The material was judged to be homogeneous. The level of homogeneity proved satisfactory for a sample volume of 0.1 ml. The uncertainty incorporates the sample standard deviation combined with the uncertainty calculated from homogeneity and stability studies.
To ensure sufficient homogeneity of the sample follow the Instruction for the correct use.

Names of certifying officers:

Laboratory: Ognyan Todorov

Manager: Krassimira Taralova

This certificate has been computer generated and does not signated

This document is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO Guide 31, ISO Guide 35,and Eurachem / CITAC Guides

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
- Accredited according to ISO 17034

Signed by: Taralova, Chemical Production Manager

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