spectracer

Certificate of Analysis

Certified Reference Material for standardization of volumetric solutions

Lot N: 1184939 Barcode: 61320901 Certification Date: 12.12.2025

Description of the CRM:	**Trometamol - $C_4H_{11}O_3N$**
CAS N:	77-86-1
Ref N:	CM 53755
Calibration method:	CRM's calibration procedure *WQP 5.15.1/11* Characterization procedure/assignment of property value of substances by classical analysis
Assay:	99.99% +/- 0.4% (w/w) *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:	BAM RefN 93440 LotN BCCK0309 The metrological traceability is assured through calibration by classical volumetric analysis, using standard solutions prepared from a certified reference material traceable to SI. All contributions in relation to the preparation of standard solutions are considered when evaluating the uncertainty. All analytical balances used for the preparation of the solution are calibrated yearly under an in-house procedure WQP 5.15.1.3 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
Storage Conditions:	Store under normal laboratory conditions, at temperatures between 15°C to 25°C
Expiry date:	12.01.2031

Intended use:

For Laboratory Use Only

This CRM is intended for:

- Standardization of volumetric solutions, including secondary reference standards in accordance with the Pharmacopoeia (PhEur, BP and USP)
- Validation of analytical methods
- Preparation of "working reference samples"
- Detection limit and linearity studies

This CRM cannot be used as purity standard or pH standard.

Instructions for the correct use of this reference material:

The CRM should be thoroughly mixed by repeatedly inverting and rotating the bottle horizontally before removing a test portion for analysis.
This material may be used directly from the bottle without pre-treatment. No additional drying is required. The material should be stored in its tightly sealed, original bottle in a cool, dry location.

Stability and storage:

Tests show the material to be dry as-received and will not adsorb appreciable water when exposed to a 90 % relative humidity atmosphere for short terms.

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.

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.
A minimum mass of 50 mg should be used for analytical determinations to be related to the assay values in this Certificate of Analysis. Samples less than 50 mg are not recommended in order to avoid possible heterogeneity with smaller sample sizes.

Names of certifying officers:
Laboratory: Dinko Gospodinov
Manager: Krassimira Taralova

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

This document is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO 33401 , ISO 33405, EA 4/02 and Eurachem / CITAC Guides

Signed by: Taralova, Chemical Production Manager