

CERTIFICATE OF GRAVIMETRIC PREPARATION

PRODUCT: Concentrate to make Calcium Standard 5000802
in accordance with European Pharmacopoeia

PRODUCT No.: 5000802C

MATRIX: H₂O + tr. Acetic Acid

LOT NO.: 5802C23J1

DATE OF PREPARATION: 26th September 2023

EXPIRY DATE: 28th September 2024

DENSITY VALUE: 1.001 g/ml @ 20°C

PREPARATION OF CONCENTRATE:

All standard components have been pre-qualified/verified before use. All analytical measuring devices and instrumentation have been pre-calibrated. The actual concentrations reported below are based on this preparation methodology and compound impurities.

Analyte	Raw Material	Nominal mg/L	Actual mg/kg
Calcium, as Ca	Calcium Carbonate	1000	1001 ± 0.2 %

1001 mg/kg is equivalent to 1002 mg/L @ 20°C

The expanded uncertainty (k=2) due to weighing, volumetric preparation and homogeneity is calculated in compliance with EURACHEM/CITAC Guide: Quantifying Uncertainty in Analytical Measurements as ± 0.2 %. All values are verified by ICP-MS analysis using externally sourced ISO 17034 accredited Certified Reference Materials as calibrants/quality controls where possible.

DILUTION INSTRUCTIONS FOR PREPARATION OF EP 5000802 (100ppm Calcium Alcoholic)

1. To prepare EP 5000802 (100ppm Calcium Alcoholic) dilute this solution to 10 times it's volume with Alcohol R.
2. Prepare the dilute solution immediately before use.

TRACEABILITY IN THE PRODUCTION OF THIS STANDARD

This product was prepared gravimetrically on a mass/mass basis. The solute was weighed on a balance calibrated by Reagecon engineers using mass standards traceable to the National and International primary standard of mass. Reagecon holds ISO 17025 accreditation for calibration of non-automatic weighing machines. The resulting Balance Certificate of Calibration was issued in accordance with the requirements of ISO/IEC 17025. The balance was calibrated under monitored environmental conditions and atmospheric pressure. Tests were performed for capacity, readability, repeatability, eccentricity, and linearity.

TEST METHOD:

The mean result of this standard was verified using a calibrated ICP-MS system according to an in-house test method. The result reported in this certificate was confirmed by analysis of a sample of this lot taken at time of manufacture. The density of this standard was determined using a high-performance calibrated density meter.

This certificate relates solely to the lot number given above.

Approved By: QC Technician

A handwritten signature in black ink, appearing to read 'Diana Horowitz', is written over the printed name 'Diana Horowitz'.

Date: 28th September 2023

This certificate must not be reproduced except in full.