

CERTIFICATE OF GRAVIMETRIC PREPARATION

PRODUCT: Concentrate to make Sulphate Standard 5002800
in accordance with European Pharmacopoeia

PRODUCT No.: 5002800C

MATRIX: H₂O

LOT NO.: 5280C24C1

DATE OF PREPARATION: 05th March 2024

EXPIRY DATE: 28th March 2025

DENSITY VALUE: 1.000 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
Sulphate, as SO ₄ ²⁺	Potassium Sulphate	1000	1000 ± 0.2 %

1000 mg/kg is equivalent to 1000 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 IC analysis using externally sourced ISO 17034 accredited Certified Reference Materials as calibrants/quality controls where possible.

DILUTION INSTRUCTIONS FOR PREPARATION OF Ph. Eur. 5002800 (10ppm SO₄²⁺ aq.)

1. To prepare Ph. Eur. 5002800 (Sulphate 10ppm, as SO₄²⁺) dilute this solution to 100 times it's volume with purified water.
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, using a balance calibrated by Reagecon engineers with 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 IC 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:

A handwritten signature in black ink, appearing to be 'A. H. H.', is written below the 'Approved By:' text.

Date: 07th March 2024

This certificate must not be reproduced except in full.