

CERTIFICATE OF GRAVIMETRIC PREPARATION

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

PRODUCT No.: 5002800C

MATRIX: H₂O

LOT NO.: 5280C24H1

DATE OF PREPARATION: 19th August 2024

EXPIRY DATE: 28th August 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	999 ± 0.2 %

999 mg/kg is equivalent to 999 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 balances 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: Quality Technician

A handwritten signature in dark ink, appearing to read 'gabriel', is written over a faint horizontal line.

Date: 17th September 2024

This certificate must not be reproduced except in full.