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# **CERTIFICATE OF GRAVIMETRIC PREPARATION**

PRODUCT:	Concentrate to make Ammonium Standard 5000300
	in accordance with European Pharmacopoeia
PRODUCT No.:	5000300C
MATRIX:	H <sub>2</sub> O
LOT NO.:	530C24E1
DATE OF PREPARATION:	23 <sup>rd</sup> May 2024
EXPIRY DATE:	28 <sup>th</sup> May 2025
DENSITY VALUE:	0.998 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/kg	Actual mg/kg
Ammonium, as NH <sub>4</sub>	Ammonium Chloride	250.4	$250.3 \pm 0.2$ %

#### 250.3 mg/kg is equivalent to 249.9 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  $\pm$  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. 5000300 (100ppm NH4 aq.)

- 1. To prepare Ph. Eur. 5000300 (Ammonium 100ppm, as NH<sub>4</sub>) dilute this solution to 2.5 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 inhouse 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 highperformance calibrated density meter.

This certificate relates solely to the lot number given above.

Approved By: QC Supervisor

Atto

Date: 08th June 2024

This certificate must not be reproduced except in full.