

## **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.:** 530C24H1

**DATE OF PREPARATION:** 14<sup>th</sup> August 2024

**EXPIRY DATE:** 28<sup>th</sup> August 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	250.2 ± 0.2 %

**250.2 mg/kg is equivalent to 249.8 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. 5000300 (100ppm NH<sub>4</sub> 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 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 in a cursive style.

**Date:** 19<sup>th</sup> August 2024

This certificate must not be reproduced except in full.