



Certificate of Analysis

European Pharmacopoeia

Phosphate Buffer Solution pH 9.00 ± 0.10 @ 20°C

 Product No:
 4008300
 Date of Measurement:
 27/05/2025

 Lot No:
 483025E1
 Date of Sample Receipt:
 27/05/2025

 Expiry Date*:
 28/05/2027
 Date of Manufacture*:
 27/05/2025

Specification: Mean Measured Value:

<mark>8.9 - 9.1 @ 20°C</mark> 9.0 pH @ 20°C

Method:

The result reported above was determined by analysis of a sample of this lot taken at time of manufacture. Test Method used was TPPHB. Measured with a combination glass electrode after multiple point calibration with reference materials. This certificate relates solely to the sample as received by the laboratory, bearing the product code and lot number given above. The uncertainty of measurement has been calculated not to exceed ± 0.010pH at 95% confidence level, i.e. coverage factor k =2.

Metrological Traceability:

The test result is traceable to Standard Reference Material of National Institute of Standards and Technology (USA), SRM 191d-I Sodium Bicarbonate, SRM 191d-II Sodium Carbonate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate.

Accreditation:

Reagecon Diagnostics Ltd. is accredited to ISO 17025 by the American Association for Laboratory Accreditation, under scope 6739.03, for the test method, TPPHB, used to generate the above result. This accreditation deems Reagecon competent on a quality systems level and a technical level to perform the tests on the scope of accreditation. Reagecon has the Quality Management Systems in place to ensure that each individual test result generated using TPPHB is technically valid and is supported by appropriate uncertainty measurements.

Date of Issue of the Certificate:

29/05/2025

QC Supervisor

Arth

ASHTON Colin

All raw materials used to prepare this product are of high purity.

*The detail above is based on information supplied in writing by Reagecon Manufacturing.

Tested by Reagecon Quality Control Laboratories for Reagecon Manufacturing

This Certificate must not be reproduced except in full. Rev-QL002