

Dissolution Accessories, PO Box 173, 4900 AD, Oosterhout, The Netherlands

Tel + 31 (0) 162-471485 Fax + 31 (0) 162-471486

CERTIFICATE OF ANALYSIS

PRODUCT: ACETATE BUFFER pH 4.50 @25°C

DISSOLUTION MEDIA CONCENTRATE

PRODUCT No.: DMC022-10

LOT NO: DMC22119L1

DATE OF TEST: 28/11/2019

EXPIRY DATE: 28/11/2021

MEAN pH VALUE: $4.52@25^{\circ}$ C

SPECIFICATION: pH 4.48 – 4.52 @25°C after dilution

DENSITY (g/ml): 1.0274 @25°C

COMPOSITION: Sodium Acetate

Glacial Acetic Acid

pH MEASUREMENT: Tested in accordance with in-house method TPPHB.

Measured with a combination glass electrode after multiple

point calibration with reference materials.

TRACEABILITY: Standard buffer solutions are certified traceable to the

following U.S. National Institute of Standards and Technology, SRM 185h Potassium Hydrogen Phthalate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM

Derdre Madigan

186-II-g Disodium Hydrogen Phosphate.

This certificate relates solely to the lot number given above. The uncertainty of measurement has been calculated not to exceed ± 0.02 pH units at 95% confidence level.

This product complies with the USP requirements for dissolution media when diluted with purified water as instructed.

Approved By: QC Technician

Date: 28/11/2019