

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

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CERTIFICATE OF ANALYSIS

PRODUCT: ACETATE BUFFER pH 4.50 @25°C

DISSOLUTION MEDIA CONCENTRATE

PRODUCT No.: DMC022-25

LOT NO: DMC2214M1

DATE OF TEST: 03rd February 2015

EXPIRY DATE: 28th December 2016

MEAN pH VALUE: 4.49@25°C

SPECIFICATION: pH 4.45 – 4.55 @ 25°C after dilution

DENSITY (g/ml): 1.0256 @ 25°C

COMPOSITION: Sodium Hydroxide (30%)

80% 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

Nargaret Dornan

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

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 Supervisor

Date: 03rd February 2015