

CERTIFICATE OF ANALYSIS

PRODUCT: SIMULATED INTESTINAL FLUID (without enzyme)
DISSOLUTION MEDIA CONCENTRATE

PRODUCT No.: DMC031-06

LOT NO: DMC31117D1

DATE OF TEST: 11/04/2017

EXPIRY DATE: 28/04/2019

MEAN pH VALUE: 6.51 @25°C

SPECIFICATION: pH 6.50 - 6.60 @25°C after dilution

DENSITY (g/ml): 1.1259 @25°C

COMPOSITION: Potassium dihydrogenorthophosphate
Sodium Hydroxide

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 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 & EP requirements for dissolution media when diluted with purified water as instructed.



Approved by:

Remco Klop - Quality Manager

Date: 11/04/2017