Certificate of Analysis

PRODUCT:	SIMULATED GASTRIC FLUID (without enzyme) DISSOLUTION MEDIA CONCENTRATE
PRODUCT No.:	DMC030-06
LOT NO:	DMC3010M1B
DATE OF TEST:	28-06-2017
EXPIRY DATE:	28-06-2019
MEAN MOLARITY:	0.07084M after dilution
SPECIFICATION:	0.07068 – 0.07139M HCL
METHOD:	Tested by potentiometric titration, to in-house method TPATA.
TRACEABILITY:	This volumetric solution was checked by means of Sodium Hydroxide Analytical Volumetric Standard. This volumetric standard is directly traceable to a Standard Reference Material of National Institute of Standards and Technology (USA), 84L Potassium Hydrogen Phthalate. All raw materials used to prepare this product are of high purity.
MEAN MOLARITY:	0.1053M after dilution
SPECIFICATION:	0.1047 – 0.1058M Chloride
METHOD:	Tested by potentiometric titration, to in-house method TPATPPT1.
TRACEABILITY:	This volumetric solution was checked by means of Silver Nitrate Analytical Volumetric Standard. This volumetric standard is directly traceable to a Standard Reference Material of National Institute of Standards and Technology (USA), 919b Sodium Chloride. All raw materials used to prepare this product are of high purity.
MEAN pH VALUE	1.2 @ 25°C
SPECIFICATION:	pH 1.1 – 1.3 @ 25°C

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 186-II-g Disodium Hydrogen Phosphate.
DENSITY (g/ml):	1.0614 @25°C
COMPOSITION:	Sodium Chloride Hydrochloric Acid

The pH value outlined on 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: 26/06/2017