

CERTIFICATE OF ANALYSIS

PRODUCT:	SIMULATED GASTRIC FLUID (without enzyme) DISSOLUTION MEDIA CONCENTRATE
PRODUCT No.:	DMC030-25
LOT NO:	DMC3014M1
DATE OF TEST:	20/01/2015
EXPIRY DATE:	28/12/2016
MEAN MOLARITY:	0.07094M 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:	0.1053 M 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

DISSOLUTION ACCESSORIES

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MEAN pH VALUE:	1.1 @25°C
SPECIFICATION:	pH 1.1 – 1.3 @25°C after dilution
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 189c Potassium Tetraoxalate and SRM 185i Potassium Hydrogen Phthalate.
DENSITY (g/ml):	1.0662 @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:
Rosemary Coney
QA Officer

Rosemary Coney

Date: 20/01/2015