

CERTIFICATE OF ANALYSIS

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| PRODUCT: | SIMULATED GASTRIC FLUID (without enzyme) DISSOLUTION MEDIA CONCENTRATE |
| PRODUCT No.: | DMC030-06 |
| LOT NO: | DMC3016C1 |
| DATE OF TEST: | 25/03/2016 |
| EXPIRY DATE: | 28/03/2018 |
| MEAN MOLARITY: | 0.07112M 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: | 0.1048M 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,
PO Box 173,
4900 AD,
Oosterhout,
The Netherlands

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

MEAN pH VALUE: 1.3@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): 1.0612g/ml @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 & EP requirements for dissolution media when diluted with purified water as instructed.

Approved By:  QC Supervisor

Date: 25/03/2016