

## Certificate of Analysis

<b>PRODUCT:</b>	SIMULATED GASTRIC FLUID (without enzyme) DISSOLUTION MEDIA CONCENTRATE
<b>PRODUCT No.:</b>	DMC030-25
<b>LOT NO:</b>	DMC3012E12
<b>DATE OF TEST(2):</b>	28/09/2016
<b>EXPIRY DATE:</b>	28/09/2018
<b>MEAN MOLARITY:</b>	0.07106M after dilution
<b>SPECIFICATION:</b>	0.07068 – 0.07139M HCL
<b>METHOD:</b>	Tested by potentiometric titration, to in-house method TPATA.
<b>TRACEABILITY:</b>	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.
<b>MEAN MOLARITY:</b>	0.1057M after dilution
<b>SPECIFICATION:</b>	0.1047 – 0.1058M Chloride
<b>METHOD:</b>	Tested by potentiometric titration, to in-house method TPATPPT1.
<b>TRACEABILITY:</b>	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:** 1.1 @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 185h Potassium Hydrogen Phthalate, SRM 186-I-g Potassium Dihydrogen Phosphate and SRM 186-II-g Disodium Hydrogen Phosphate.

**DENSITY (g/ml):** 1.0623 @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  $\pm 0.02$  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: 28-09-2016

---

Dissolution accessories is a ProSense BV Brand

ProSense BV • P.O. Box 173 • 4900 AD Oosterhout • The Netherlands  
www.dissolutionaccessories.com • info@dissolutionaccessories.com