

Shannon Free Zone Shannon Co. Clare

Ireland

Phone +353 61 472622 Fax +353 61 472642 Web www.reagecon.com

CERTIFICATE OF ANALYSIS

PRODUCT: SIMULATED GASTRIC FLUID (without enzyme)

DISSOLUTION MEDIA

PRODUCT No.: DB12-121

LOT NO: DB1224L1

DATE OF TEST: 13/11/2024

EXPIRY DATE: 28/11/2026

MEAN pH VALUE: 1.16 @ 25 °C

pH SPECIFICATION: 1.00 – 1.40 @ 25 °C

pH MEASUREMENT: Tested in accordance with in-house method. 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 and SRM 189c Potassium Tetraoxalate.

MEAN MOLARITY: 0.0809 M Hydrochloric Acid

SPECIFICATION: 0.0800 – 0.0880 M Hydrochloric Acid

METHOD: Tested by potentiometric titration, to in-house method.

TRACEABILITY: This product was checked by means of a 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.



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CERTIFICATE OF ANALYSIS

MEAN MOLARITY: 0.0358 M Sodium Chloride

SPECIFICATION: 0.0324 - 0.0359 M Sodium Chloride

METHOD: Tested by argentometric titration, to in-house method.

TRACEABILITY: This Solution was tested by precipitation titration with Silver Nitrate

Analytical Volumetric Standard. This volumetric standard is directly traceable to Standard Reference Material of National Institute of Standards and Technology (USA), SRM 919b Sodium Chloride.

COMPOSITION: Sodium Chloride

Hydrochloric Acid Purified Water

This product complies with the USP & EP requirements for dissolution media when 3.2g/l of Pepsin to is added to it.

All raw materials used to prepare this product are of high purity.

gabriel

Approved By:

QC TECHNICIAN Date: 14/11/2024

This certificate must not be reproduced except in full.