



Shannon Free Zone
Shannon
Co. Clare
Ireland

Phone +353 61 472622

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Web www.reagecon.com

CERTIFICATE OF ANALYSIS

PRODUCT:	SIMULATED GASTRIC FLUID (without enzyme) DISSOLUTION MEDIA
PRODUCT No.:	DB12-121
LOT NO:	DB1223M1
DATE OF TEST:	18/12/2023
EXPIRY DATE:	28/12/2025
MEAN pH VALUE:	1.17 @ 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:	0.0807 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: 0.0339 M Sodium

SPECIFICATION: 0.0324 - 0.0359 M Sodium

METHOD: Tested by ICP-MS, to in-house method.

TRACEABILITY: This product was checked by means of an ISO 17034 Certified Reference Material. This standard is directly traceable to a Standard Reference Material of National Institute of Standards and Technology (USA), 3152a Sodium.

COMPOSITION: Sodium Chloride
Hydrochloric Acid
Purified Water

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

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

Approved By:

A handwritten signature in black ink, appearing to be 'A. Thornton'.

QC Supervisor

Date: 21/03/2024

This certificate must not be reproduced except in full.