CERTIFICATE OF ANALYSIS

PRODUCT: SIMULATED GASTRIC FLUID (without enzyme)
DISSOLUTION MEDIA

PRODUCT No.: DB12-121

LOT NO: DB1223C1

DATE OF TEST: 04/04/2023

EXPIRY DATE: 28/03/2025

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: 0.0855M Hydrochloric Acid

SPECIFICATION: 0.0800 – 0.0880M 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.

Reagecon

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CERTIFICATE OF ANALYSIS

MEAN MOLARITY: 0.0352M Sodium

SPECIFICATION: 0.0324 - 0.0359M 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 to is added to it.

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

Approved By: QC Technician

Date: 11/04/2023

This certificate must not be reproduced except in full.