

Certificate of Analysis

**Simulated Gastric Fluid (without Pepsin)
0.2% (w/v) Sodium Chloride in 0.7% (v/v) Hydrochloric Acid****Lot Number:** 2210J14**Product Number:** 7108**Manufacture Date:** OCT 31, 2022**Expiration Date:** OCT 2024

To prepare Simulated Gastric Fluid TS from this product, add 3.2 grams of purified Pepsin (derived from porcine stomach mucosa, with an activity of 800 to 2500 units per mg of protein) per liter of this solution immediately before use. Simulated Gastric Fluid TS does not keep well after the addition of Pepsin. All lots of this product are certified to meet the specifications of the United States Pharmacopeial Convention, Inc. (USP) given in The United States Pharmacopeia for Simulated Gastric Fluid TS, except that the PEPSIN (3.2 grams per liter) WAS NOT ADDED in order to improve stability and increase the shelf life of this product.

Name	CAS#	Grade
Water	7732-18-5	ACS/ASTM/USP/EP
Hydrochloric Acid	7647-01-0	ACS
Sodium Chloride	7647-14-5	ACS

Test	Specification	Result	NIST SRM#
Appearance	Colorless liquid	Passed	
Assay (vs. Silver Nitrate/Potassium Chromate)	0.1138-0.1238 N at 20°C	0.1142 N at 20°C	999
pH at 25°C (Method: SQCP027, SQCP033)	1.0-1.4	1.2	185i, 186-I-g, 186-II-g

Volumetric glassware complies with Class A tolerance requirements of ASTM E 288 and NIST Circular 434; it is calibrated before first use and recalibrated regularly in accordance with ASTM E 542 and NIST Procedure NBSIR 74-461. Balances are calibrated regularly with weights certified traceable to the NIST national mass standard. Thermometers and temperature probes are calibrated before first use and recalibrated regularly with a thermometer traceable to NIST standards. All products are prepared according to master documents that assure manufacture according to validated methods. Batch records document raw material traceability and production and testing history for each lot manufactured.

Part Number	Size / Package Type	Shelf Life (Unopened Container)
7108-32	1 L natural poly	24 months

Recommended Storage: 15°C - 30°C (59°F - 86°F)

Myrlande Gilles (10/31/2022)

Quality Control

This Certificate of Analysis is designed to comply with ISO Guide 31 "Reference Materials -- Contents of Certificates and Labels."

This test report shall not be reproduced, except in full, without the written approval of Ricca Chemical Company.