

Certificate of Analysis

Sodium Chloride, 0.9% (w/v), Isotonic Saline Suitable for Use as Blood Bank Saline

Lot Number: 4401H44

Product Number: 7210

Manufacture Date: JAN 11, 2024

Expiration Date: DEC 2025

For In Vitro Diagnostic Use. Suitable for use as isotonic Blood Bank Saline, as a general purpose red blood cell washing fluid to remove plasma proteins, and as a cell diluent. May be suitable for other laboratory applications.

Manufacturing controls, including submicron filtration, are in place to minimize particle count, fungal and bacterial content, and heavy metal contamination. There is no observable hemolysis with human red blood cells. This product is nonsterile and contains no preservatives or inhibitors. Low temperature storage (1 - 8°C) will minimize increase in microbiological content as this product ages.

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

Test	Specification	Result	NIST SRM#
Appearance	Colorless liquid	Passed	
Assay (vs. Silver Nitrate/Potassium Chromate)	8.98-9.00 g/L	9.00 g/L	999

Specification	Reference
Standard Isotonic Sodium Chloride Solution for Immunohematologic Testing Saline TS	NCCLS (ASI/BB-1) USP (N/A)

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)
7210-1	4 L natural poly	24 months
7210-16	500 mL natural poly	24 months
7210-32	1 L natural poly	24 months

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



Paul Brandon (01/11/2024)

Production Manager

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

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