

BAXTER CLEVELAND PRODUCT CERTIFICATION

911 North Davis
Cleveland, MS 38732

(2F7121 / 2F7122 / 2F7123 / 2F7124 / 2F7125)

CODE <u>2F7122</u>	BATCH <u>G1432210</u>	MFG. DATE <u>11/10/20</u>	STERILIZATION DATE <u>11/10/20</u>
PLANT OF MANUFACTURE CLEVELAND, MS		EXPIRY DATE <u>Jan 2023</u>	

DESCRIPTION

0.9% Sodium Chloride, USP

TEST	LIMITS	SAMPLE RESULTS	DATE PASSED
BACTERIAL ENDOTOXIN (PYROGEN)	CONTROL LIMIT (Eu/mL)		
13-01-10-313	<0.5 EU/ml = Pass	EU/ml <u><0.01</u>	<u>1/14/20</u>
STERILITY PARAMETRIC RELEASE	PASS	PASSED	<u>1/10/20</u>
PARTICLE ANALYSIS 20-03-07-006	NMT 25 part/mL $\geq$ 10 μ m	part/mL <u>0</u>	<u>1/13/20</u>
	NMT 3 part/mL $\geq$ 25 μ m	part/mL <u>0</u>	

PARAMETRIC RELEASE IN ACCORDANCE WITH U.S. FDA REQUIREMENTS

CHEMICAL RESULTS 3-15-19-156 ISSUE DATE 11/13/18

REFERENCE	TEST	LIMITS	RESULT
11-21-16-003	pH @ 25°C	4.5-7.0	<u>5.6</u>
11-07-19-001 or 11-16-03-005 or 11-16-03-016	NaCl Assay	8.55-9.45 g/l	<u>8.97</u> g/l
11-20-19-006	Sodium ID - USP	Positive	Positive
<u>NAI per 1/14/20</u>			

THIS PRODUCT WAS MANUFACTURED ACCORDING TO CURRENT GMP, FULLFILLS THE REQUIRMENTS OF THE MASTER PRODUCTION DOCUMENT AND TESTED TO USP COMPLIANCE.

DATE BATCH RELEASED 11/14/20PREPARED BY/DATE Blederson 1/14/20QUALITY MANAGEMENT SUPERVISOR Kline 1/14/20

