BAXTER CLEVELAND PRODUCT CERTIFICATION

911 North Davis
Cleveland, MS 38732
(2F7121 / 2F7122 / 2F7123 / 2F7124 / JF7123 / JF7124)

CODE	BATCH	MFG. DATE	STERILIZATION DATE
2F7124	G157643	6/25/22	6/25/22
PLANT OF MANUFACTURE: CLEVELAND, MS		EXPIRY DATE: Jun 2025	

DESCRIPTION

0.9% Sodium Chloride, USP

TEST	LIMITS	SAMPLE RESULTS	DATE PASSED
BACTERIAL ENDOTOXIN (PYROGEN) 13-01-10-313	CONTROL LIMIT (Eu/mL) <0.5 EU/ml = Pass	<0.01 EU/ml	6/27/22
STERILITY PARAMETRIC RELEASE	PASS	PASSED	6/25/22
PARTICLE ANALYSIS 20-03-07-006	NMT 25 part/mL ≥ 10 µm	0 part/mL	6/27/22
	NMT 3 part/mL > 25 µm	0 part/mL	

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	5.5
11-07-19-001 or 11-16-03-005 or 11-16-03-016	NaCl Assay	8.55-9.45 g/l	8.87 g/l
11-20-19-006	Sodium ID - USP	Positive	Positive

NA (MR) 6/30/22

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

DATE BATCH RELEASED 6/30/22

PREPARED BY/DATE BRobinson 6/30/22

QUALITY MANAGEMENT SUPERVISOR ~~C Hogan~~ C. Hogan 7.5.2022

NL C. Hogan 7.5.2022

MDM

1. Code, Batch, Mfg. Date, Sterilization Date, and Expiry Date - Enter the information from Production Report of batch required.

2. Test:

   Bacterial Endotoxin – Enter the bacterial endotoxin test results. Enter the date passed (date the bacterial endotoxin testing was complete) from the bacterial endotoxin test report for the batch.

   Sterility – Enter the date product was sterilized.

   Particle Analysis – Enter the sample results and the date passed from the particle analysis record for the batch.

3. Chemical Results - Enter issue date of the applicable 3-15 specification. All results should be verified against the limits in the applicable 3-15 specification. All test results are retrieved from the EOB chemical testing. Fill in test results.

Note: Multiple test results may be averaged by Release Clerk and the average entered on this certification. (Example - multitank and stability batches).

Note: NaCl Assay- Circle the 11 spec used for testing.

4. Date Batch Released - Fill in date batch was released.

5. Prepared By/Date - Dated signature of person entering information.

Note: Signature of Release Clerk indicates the results have been verified against the results listed on the chemical final analysis and the applicable 3-15 chemical testing specification, the results listed on the Particle Analysis Report and results listed on the Bacterial Endotoxin report.

6. N/A sections not used.

7. Quality Management Supervisor - Signature of Quality Management Supervisor or delegate verifying the Batch #, Code, Manufacturer Date, Expiration Date, and Batch Release Date documented matches the information documented on the Production Record. Individual will and verify that all test results listed are within specification and/or SOP limits.

DESCRIPTION OF CHANGE		
Name change.		
REASON FOR CHANGE		
Update approval signature. Periodic Review Response.		
CHANGE HISTORY		
CHANGE #	**ISSUE DATE**	**DESCRIPTION OF CHANGE**
20-2021	07/16/20	Add JF7123 and JF7124 to form CLF-03-148.
20-1012	04/16/20	Update MDM to include specific information for the approver to verify.
19-0877	04/12/19	13-1-V is obsolete and adding 11-21-16-005 test to Particle Analysis. Eu/mL is being added to sample results for Bacterial Endotoxin and part/mL is being added to Particle Analysis sample results. 11-20-19-007 is being deleted because it's not used for these codes. Add change history to form.

APPROVALS ON FILE	
ROLE	**NAME**
SME/Release Clerk	Beverly Robinson
Approver	Kellie Cutts
Concurrer	Ellen Soliz