BAXTER CLEVELAND CERTIFICATE OF ANALYSIS

911 North Davis
Cleveland, MS 38732

(2F7121 / 2F7122 / 2F7123 / 2F7124 / JF7123 / JF7124)

CODE	BATCH	MFG. DATE	STERILIZATION DATE
2F7124	G168052	12-4-23	12-4-23
MANUFACTURING FACILITY: CLEVELAND, MS		EXPIRY DATE: 2026-12	

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	12-7-23
STERILITY PARAMETRIC RELEASE	PASS	PASSED	12-4-23
PARTICLE ANALYSIS 20-03-07-006	NMT 25 part/mL ≥ 10 µm	2 part/mL	12-6-23
	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	5.7
11-07-19-001 or 11-16-03-005 or 11-16-03-016	NaCl Assay	8.55-9.45 g/l	8.94 g/l
11-20-19-006	Sodium ID - USP	Positive	Positive
			NA M. Sims 12-15-23

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

DATE BATCH RELEASED 12-14-23

PREPARED BY/DATE M. Sims 12-15-23 IN Training
Hampton 12-15-23

QUALITY MANAGEMENT SUPERVISOR C. Hogan 12.18.2023

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 Chemical or Particle Analysis test results will be averaged per CLF-02-1293, *BaxLIMS Batch Results with Averages:* Chemistry or CLF-02-1292, *BaxLIMS Batch Results with Averages: Micro.* or manually by the responsible Lab personnel. The average will be entered on this certificate.
(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 Documentation Coordinator indicates the results have been verified against the results listed on the chemical final analysis or BaxLIMS Batch Results with Averages: Chemistry and the applicable 3-15 chemical testing specification, the results listed on the Particle Analysis Report or BaxLIMS Batch Results with Averages: Micro 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		
Add Chemistry and Microforms to summarize and average final test results.		
REASON FOR CHANGE		
Corrective/Preventive Action PR# 2608966. The new forms will be utilized for averages.		
CHANGE HISTORY		
CHANGE #	**ISSUE DATE**	**DESCRIPTION OF CHANGE**
22-2049	09/16/22	Name change. Update title.
21-1779	01/11/22	Name change.
20-2021	07/16/20	Add JF7123 and JF7124 to form CLF-03-148.

APPROVALS ON FILE	
ROLE	**NAME**
SME/Release Clerk	Beverly Robinson
Approver	Curtissha Hogan
Concurrer	Kah'ya Loggins