BAXTER CLEVELAND PRODUCT CERTIFICATION

911 North Davis
Cleveland, MS 38732
(2F7121 / 2F7122 / 2F7123 / 2F7124 / 2F7125 / 2F8203 / 2F8204)

CODE 2F7124	BATCH G139663	MFG. DATE 5/13/19	STERILIZATION DATE 5/13/19
PLANT OF MANUFACTURE CLEVELAND, MS		EXPIRY DATE May 2022	

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	5/14/19
STERILITY PARAMETRIC RELEASE	PASS	PASSED	5/13/19
PARTICLE ANALYSIS 20-03-07-006 11-21-16-005	NMT 25 part/mL ≥ 10 µm	1 part/mL	5/14/19
	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	5.6
11-07-19-001 or 11-16-03-005 or 11-16-03-016	NaCl Assay	8.55-9.45 g/l	8.84 g/l
11-20-19-006	Sodium ID - USP	Positive	Positive

WNL/BR 5/16/19

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

DATE BATCH RELEASED 5/16/19

PREPARED BY/DATE BRobinson 5/16/19

QUALITY MANAGEMENT SUPERVISOR [signature] 5/16/19

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 - Dated signature of Quality Management Supervisor or delegate verifying the certificate for completeness and that all test results listed are within specification limits.

DESCRIPTION OF CHANGE		
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.		
REASON FOR CHANGE		
To comply with customer's request. To comply with new Spec Dept. requirements.		
CHANGE HISTORY		
CHANGE #	**ISSUE DATE**	**DESCRIPTION OF CHANGE**
N/A	N/A	N/A
N/A	N/A	N/A
N/A	N/A	N/A

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