

BAXTER CLEVELAND PRODUCT CERTIFICATION

911 North Davis

Cleveland, MS 38732

(2F7112 / 2F7113 / 2F7114 / 2F7115 / 2F8214)

CODE <u>2F7114</u>	BATCH <u>G138413</u>	MFG. DATE <u>2/14/19</u>	STERILIZATION DATE <u>2/14/19</u>
PLANT OF MANUFACTURE CLEVELAND, MS		EXPIRY DATE <u>Feb 2022</u>	

DESCRIPTION

Sterile Water for Irrigation, USP

TEST	LIMITS	SAMPLE RESULTS	DATE PASSED
BACTERIAL ENDOTOXIN (PYROGEN)	CONTROL LIMIT (Eu/mL)		
13-01-10-313	<0.25 EU/ml = Pass	<u>20.02</u> EU/mL	<u>2/18/19</u>
STERILITY PARAMETRIC RELEASE	PASS	PASSED	<u>2/14/19</u>
PARTICLE ANALYSIS	≥ 10 um/mL NMT 25	part/mL	<u>2/18/19</u>
20-03-07-006	≥ 25 um/mL NMT 3	<u>0</u> part/mL	
11-21-16-005		<u>0</u> part/mL	<u>2/18/19</u>

PARAMETRIC RELEASE IN ACCORDANCE WITH U.S. FDA REQUIREMENTS

CHEMICAL RESULTS 3-15-53-216 ISSUE DATE 2/26/15

REFERENCE	TEST	LIMITS	RESULT
11-21-16-003	pH at 25°C	5.0-7.0	<u>5.6</u>
11-20-15-001	Oxidizable Substances	Pass	Pass
11-22-03-007	Conductivity	NMT 5µs/cm @25±1°C	<u>1.1</u> µs/cm

THIS LOT HAS BEEN PRODUCED IN ACCORDANCE WITH PROCEDURES IN THE MASTER PRODUCTION DOCUMENT.
THIS LOT HAS BEEN PRODUCED IN ACCORDANCE WITH CURRENT USP REQUIREMENTS.

DATE BATCH RELEASED 2/19/19PREPARED BY/DATE Blahunson 2/19/19QUALITY MANAGEMENT SUPERVISOR Kurt 2/20/19

MDM

1. Code, Batch, Mfg. Date & Sterilization Date - Enter the information from Production Report of batch required.
2. Expiry Date - Enter the date of expiration from Production Report.
3. 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.

4. 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).

5. Date Batch Released - Fill in date batch was released.
6. Prepared By/Date - Sign and date when information on chart has been satisfied.

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.

7. Quality Management Supervisor - Dated signature of Quality Management delegate listed in CL-02-07-002 verifying the certificate for completeness and that all test results listed are within specification limits.

Note: N/A sections not used.

DESCRIPTION OF CHANGE		
Remove 13-01-V. Add Eu/mL to Sample Results. Add 11-21-16-005 to Particle Analysis section and add part/mL to Sample Results. Add change history to form.		
REASON FOR CHANGE		
To comply with new Spec Dept. requirements. To comply with customer 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 Stillion	
Concurren	Ellen Soliz	