BAXTER CLEVELAND PRODUCT CERTIFICATION

911 North Davis
Cleveland, MS 38732
(2F7112 / 2F7113 / 2F7114 / 2F7115)

CODE	BATCH	MFG. DATE	STERILIZATION DATE
2F7114	G141697	9/29/19	9/29/19
PLANT OF MANUFACTURE: CLEVELAND, MS		EXPIRY DATE: Sep 2022	

DESCRIPTION

Sterile Water for Irrigation, USP

TEST	LIMITS	SAMPLE RESULTS	DATE PASSED
BACTERIAL ENDOTOXIN (PYROGEN) 13-01-10-313	CONTROL LIMIT (Eu/mL) <0.25 EU/ml = Pass	<0.02 EU/mL	10/1/19
STERILITY PARAMETRIC RELEASE	PASS	PASSED	9/29/19
PARTICLE ANALYSIS 20-03-07-006	≥ 10 um/mL NMT 25	8 part/mL	10/1/19
	≥ 25 um/mL NMT 3	0 part/mL	

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	5.6
11-20-15-001	Oxidizable Substances	Pass	Pass
11-22-03-007	Conductivity	NMT5µs/cm @25±1°C	1.1 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 10/3/19

PREPARED BY/DATE BJohnson 10/3/19

QUALITY MANAGEMENT SUPERVISOR 10-3-19

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

Note: N/A sections not used.

DESCRIPTION OF CHANGE		
Update MDM to include specific information for the approver to verify.		
REASON FOR CHANGE		
Comply with CL-03-01-039.		
CHANGE HISTORY		
CHANGE #	**ISSUE DATE**	**DESCRIPTION OF CHANGE**
19-0876	04/12/19	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.
N/A	N/A	N/A
N/A	N/A	N/A

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