BAXTER CLEVELAND CERTIFICATE OF ANALYSIS

911 North Davis
Cleveland, MS 38732
(2F7112 / 2F7113 / 2F7114 / JF7113 / JF7114)

CODE	BATCH	MFG. DATE	STERILIZATION DATE
2F7114	G169615	2·28·24	2·28·24
MANUFACTURING FACILITY: CLEVELAND, MS		EXPIRY DATE: 2027-02	

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	3·12·24
STERILITY PARAMETRIC RELEASE	PASS	PASSED	2·28·24
PARTICLE ANALYSIS 20-03-07-006	Instrumental Particle Counts [ ] N/A		
	NMT 25 particles/mL ≥ 10 µm	particles/mL: 0 part/mL	3·6·24
	NMT 3 particles/mL ≥ 25 µM	particles/mL: 0 part/mL	3·6·24
	Microscopic Particle Counts [ ] N/A		
	NMT 12 particles/mL ≥ 10 µm	particles/mL	
	NMT 2 particles/m: ≥ 25 µm	particles/mL	

PARAMETRIC RELEASE IN ACCORDANCE WITH U.S. FDA REQUIREMENTS

CHEMICAL RESULTS 3-15-53-216 ISSUE DATE 4·30·21

REFERENCE	TEST	LIMITS	RESULT
11-21-16-003	pH at 25°C	5.0-7.0	5.6
11-22-20-013	Total Organic Carbon	8.00 mg/L C	0.15
11-22-03-007	Conductivity	NMT5µs/cm @25±1°C	1.3 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 3·12·24

PREPARED BY/DATE Frank 3·12·24

QUALITY MANAGEMENT SUPERVISOR C. Hogan 03/25/2024

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 for the Test method used for Particle Analysis. "NA" the test not used.

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 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).

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 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.

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		
Name change. Add Chemistry and Micro forms to summarize and average final test results.		
REASON FOR CHANGE		
Update approval signature. Corrective/Preventative Action PR# 2608966. The new forms will be utilized for averages.		
CHANGE HISTORY		
CHANGE #	**ISSUE DATE**	**DESCRIPTION OF CHANGE**
22-1458	06/28/22	Title update and MDM.
21-1869	08/06/21	Add option to record relevant PA test result.
21-1093	05/10/21	Update chemical test & reviewer.

APPROVALS ON FILE	
ROLE	**NAME**
SME/Documentation Coord	Beverly Robinson
Approver	Curtissha Hogan
Concurrer	LaJuana Long