

## BAXTER CLEVELAND CERTIFICATE OF ANALYSIS

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

|                                         |                       |                                |                                   |
|-----------------------------------------|-----------------------|--------------------------------|-----------------------------------|
| CODE <u>2F7114</u>                      | BATCH <u>C-165198</u> | MFG. DATE <u>7/13/23</u>       | STERILIZATION DATE <u>7/13/23</u> |
| MANUFACTURING FACILITY<br>CLEVELAND, MS |                       | EXPIRY DATE<br><u>Jul 2026</u> |                                   |

DESCRIPTION

Sterile Water for Irrigation, USP

| TEST                                                    | LIMITS                                          | SAMPLE RESULTS           | DATE PASSED    |
|---------------------------------------------------------|-------------------------------------------------|--------------------------|----------------|
| BACTERIAL<br>ENDOTOXIN<br>(PYROGEN)<br><br>13-01-10-313 | CONTROL LIMIT (Eu/mL)<br><br><0.25 EU/ml = Pass | <u>&lt;0.02</u> EU/mL    | <u>7/17/23</u> |
| STERILITY<br>PARAMETRIC<br>RELEASE                      | PASS                                            | PASSED                   | <u>7/13/23</u> |
| PARTICLE<br>ANALYSIS<br>20-03-07-006                    | Instrumental Particle Counts [ ] N/A            |                          |                |
|                                                         | NMT 25 particles/mL ≥ 10 µm                     | particles/mL<br><u>1</u> | <u>7/17/23</u> |
|                                                         | NMT 3 particles/mL ≥ 25 µM                      | particles/mL<br><u>0</u> | <u>7/17/23</u> |
|                                                         | Microscopic Particle Counts [X] 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            | <u>5.5</u>       |
| 11-22-20-013 | Total Organic Carbon | 8.00 mg/L C        | <u>0.13</u>      |
| 11-22-03-007 | Conductivity         | NMT 5µs/cm @25±1°C | <u>1.3</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

20  
7/18/23

WDBR 7/20/23

PREPARED BY/DATE

B. Johnson 7/20/23

QUALITY MANAGEMENT SUPERVISOR

C. Hoggin 7-20-2023

**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  |                                               |
| Concurren                                                                                                           | LaJuana Long     |                                               |