



## CERTIFICATE OF ANALYSIS

# GemPure™ Select Water for Irrigation (WFI) Quality Water (USP Grade) (Catalog Number 901-003-1X6) (Catalog Number 901-003-001)

Lot Number: M325007

Date of Manufacture: Mar2025

Storage Temperature: 2°C – 30°C

Product Expiry: Mar2027

For further manufacturing or research use only. Not for direct therapeutic use.

**Product Description:** GemPure™ Select Water for Irrigation (WFI) Quality Water (USP Grade) meets the USP monograph for Sterile Water for Irrigation packaged in bulk for commercial use.

| Test                    | Methodology         | Specification              | Analysis                   |
|-------------------------|---------------------|----------------------------|----------------------------|
| Appearance              | Visual Inspection   | Clear and colorless liquid | Clear and colorless liquid |
| Biological Testing      |                     |                            |                            |
| Endotoxin               | USP <85>, EP 2.6.14 | < 0.25 EU/mL               | < 0.0050 EU/mL             |
| Microbiological Testing |                     |                            |                            |
| Sterility               | USP <71>, EP 2.6.1  |                            |                            |
| Bacteria                |                     | No Growth                  | No Growth                  |
| Fungi                   |                     | No Growth                  | No Growth                  |
| Biochemistry Testing    |                     |                            |                            |
| Total Organic Carbon    | USP <643>           |                            |                            |
| Before Packaging        |                     | ≤ 500 ppb                  | 29 ppb                     |
| Packaged                |                     | ≤ 8000 ppb                 | 198 ppb                    |
| Physical Testing        |                     |                            |                            |
| pH @ 25°C               | USP <791>           | 4.0 – 7.0                  | 5.4                        |
| Conductivity @ 25°C     | USP <645>           |                            |                            |
| Before Packaging        |                     | ≤ 1.3 µS/cm                | 1.1 µS/cm                  |
| Packaged                |                     | ≤ 5.0 µS/cm                | 2 µS/cm                    |

The testing that has been performed as part of this lot release has been reviewed by Quality Assurance personnel and it has been confirmed that the testing meets the specifications presented on this Certificate of Analysis. This product was manufactured at an animal origin free facility. All final product processes/packaging were also performed at an animal origin free facility. This facility is ISO 13485:2016 certified.

Name Lev. Torres

Date 03APR2025

Title QA Associate I