



## CERTIFICATE OF ANALYSIS

**GemPure™ Plus Water for Injection (WFI) Quality Water**

**(USP/EP/JP Grade)**

**(Catalog Number 901-002-4X4)**

**(Catalog Number 901-002-004)**

**Lot Number: M125027**

**Date of Manufacture:** Mar2025

**Product Expiry:** Mar2027

**Storage Temperature:** 2°C – 30°C

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

**Product Description:** GemPure™ Plus Water for Injection (WFI) Quality Water (USP/EP/JP Grade) meets the USP/EP/JP monograph for Water for Injection packaged in bulk for commercial use.

| Test                           | Methodology        | Specification                              | Analysis                                   |
|--------------------------------|--------------------|--|--|
| Appearance                     | Visual Inspection  | Clear and colorless liquid                 | Clear and colorless liquid                 |
| <b>Biological Testing</b>      |                    |  |  |
| Endotoxin                      | USP<85>, EP 2.6.14 | <0.25 EU/mL                                | <0.0100 EU/mL                              |
| <b>Microbiological Testing</b> |                    |  |  |
| Sterility                      | USP <71>, EP 2.6.1 |  |  |
| Bacteria                       |                    | No Growth                                  | No Growth                                  |
| Fungi                          |                    | No Growth                                  | No Growth                                  |
| <b>Physical Testing</b>        |                    |  |  |
| Conductivity @ 25°C            | USP<645>           |  |  |
| Before Packaging               |                    | ≤1.3 μS/cm                                 | 1 μS/cm                                    |
| Packaged                       |                    | ≤5 μS/cm                                   | 1.232 μS/cm                                |
| pH @ 25°C                      | USP<791>           | 4.0 – 7.0                                  | 5.52                                       |
| <b>Biochemistry Testing</b>    |                    |  |  |
| Acidity or Alkalinity          | EP                 | No change in appearance                    | No change in appearance                    |
| Ammonium                       | EP                 | ≤0.2 ppm                                   | ≤0.2 ppm                                   |
| Calcium and Magnesium          | EP                 | Blue color produced                        | Blue color produced                        |
| Chlorides                      | EP                 | No change in appearance                    | No change in appearance                    |
| Extractable Volume             | JP<6.05>           | Volume is not less than the nominal volume | Volume is not less than the nominal volume |
| Foreign Insoluble Matter       | JP<6.06>           | See Particulate Matter                     | Pass                                       |
| Nitrates                       | EP                 | ≤0.2 ppm                                   | ≤0.2 ppm                                   |
| Oxidizable Substances          | USP/EP             | Pink color does not completely disappear   | Pink color does not completely disappear   |



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| Test                   | Methodology          | Specification           | Analysis                |
|------------------------|----------------------|-------------------------|-------------------------|
| Particulate Matter     | USP <788>, EP 2.9.19 |                         |                         |
| ≥ 25µm in size         |                      | ≤3 particles/mL         | 0 particles/mL          |
| ≥ 10µm in size         |                      | ≤25 particles/mL        | 0 particles/mL          |
| Purity                 | JP                   | Pass                    | Pass                    |
| Residue on Evaporation | EP                   | ≤3 mg (0.003%)          | <1 mg (<0.001%)         |
| Sulfates               | EP                   | No change in appearance | No change in appearance |
| Total Organic Carbon   | USP <643>            |                         |                         |
| Before Packaging       |                      | ≤500 ppb                | 4.6 ppb                 |
| Packaged               |                      | ≤8000 ppb               | 4260 ppb                |

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 920 Stillwater Rd., Suite 130, West Sacramento, CA, U.S.A., which is an animal origin free facility. All final product processes/packaging were also performed at 920 Stillwater Rd., Suite 130, West Sacramento, CA, U.S.A., an animal origin free facility. This facility is ISO 13485:2016 certified.

Karen Zuniga

Name

14 APR 2025

Date

QA Associate II

Title