



CERTIFICATE OF ANALYSIS

GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade) (Catalog Number 901-001-203, 901-001-1LT)

Lot Number: M126026

Date of Manufacture: Mar2026

Storage Temperature: 2°C – 30°C

Product Expiry: Mar2028

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

Product Description: GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade) meets the USP 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 |
| Biological Testing | | | |
| Endotoxin | USP <85>, EP 2.6.14 | < 0.25 EU/mL | < 0.0100 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 | 10 ppb |
| Packaged | | ≤ 8000 ppb | 1370 ppb |
| Physical Testing | | | |
| pH @ 25°C | USP <791> | 4.0 – 7.0 | 5.50 |
| Conductivity @ 25°C | USP <645> | | |
| Before Packaging | | ≤ 1.3 µS/cm | 0.054000001 µS/cm |
| Packaged | | ≤ 5 µS/cm | 1.477 µS/cm |
| Particulate Matter | USP <788> | | |
| ≥ 25µm in size | | ≤ 3 particles/mL | 0 particles/mL |
| ≥ 10µm in size | | ≤ 25 particles/mL | 1 particles/mL |

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.

Alejandra Peña
Name

06 Mar 2026
Date

QA Associate II
Title