



CERTIFICATE OF ANALYSIS

GemPure™ Select Water for Irrigation (WFlr) Quality Water

(USP Grade)

(Catalog Number 901-003-1X6)

(Catalog Number 901-003-001)

Lot Number: M123062

Date of Manufacture: Jun2023

Storage Temperature: 2°C – 30°C

Product Expiry: Jun2025

For further Manufacturing or Research use only. Not for direct Therapeutic use.

Product Description: GemPure™ Select Water for Irrigation (WFlr) 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 | < 0.010 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 | 3.85 ppb |
| Packaged | | ≤ 8000 ppb | 3420 ppb |
| Physical Testing | | | |
| pH @ 25°C | USP <791> | 4.0 – 7.0 | 5.5 |
| Conductivity @ 25°C | USP <645> | | |
| Before Packaging | | ≤ 1.3 µS/cm | 0.091 µS/cm |
| Packaged | | ≤ 5.0 µS/cm | 0.984 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 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.

Korrina Nicewonger
Name

06 MAY 2024
Date

QA Associate II
Title