



CERTIFICATE OF ANALYSIS

GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade)

(Catalog Number 200-888-100-KIT)

(Catalog Numbers 901-001-1LT, 901-001-101)

Lot Number: M123053

Date of Manufacture: May2023

Storage Temperature: 2°C – 30°C

Product Expiry: May2025

For Cell Culture, 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 | 0.11 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 | 4.77 ppb |
| Packaged | | ≤ 8000 ppb | 4070 ppb |
| Physical Testing | | | |
| pH @ 25°C | USP <791> | 4.0 – 7.0 | 5.6 |
| Conductivity @ 25°C | USP <645> | | |
| Before Packaging | | ≤ 1.3 μS/cm | 0.09 μS/cm |
| Packaged | | ≤ 5 μS/cm | 2.577 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.

Regina Wilson
Name

16 MAY 2024
Date

QA Specialist
Title