



CERTIFICATE OF ANALYSIS

Addendum rev2

GemPure Select Water for Injection (WFI) Quality Water

(Catalog Number 901-001-101, 901-001-201)

Lot Number: M122126

Date of Manufacture: Aug2022

Expiration Date: Aug2023

Storage Temperature: 2°C – 30°C

For Cell culture, Further Manufacturing or Research use Only. Not for Direct Therapeutic Use.

Product Description: GemPure Select Water for Injection (WFI) Quality Water 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 | <0.01 EU/mL |
| Microbiological Testing | | | |
| Sterility | USP <71>, EP 2.6.1 | | |
| Bacteria | | No Growth | No Growth |
| Fungi | | No Growth | No Growth |
| Biochemistry | | | |
| Total Organic Carbon (Before Packaging) | USP <643> | ≤ 500 ppb | 5.79 ppb |
| Total Organic Carbon (Packaged) | USP <643> | ≤ 8000 ppb | 2730 ppb |
| Physical Testing | | | |
| pH @ 25°C | USP <791> | 5.0 – 7.0 | 5.9 |
| Conductivity @ 25°C (Packaged) | USP <645> | ≤ 5 μS/cm | 1.006 μS/cm |
| Conductivity @ 25°C (Before Packaging) | USP <645> | ≤ 1.3 μS/cm | 0.096 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.

Julia Wilson
Name

QA Specialist
Title

16 MAY 2024
Date