



CERTIFICATE OF ANALYSIS

GemPure Select Water for Injection (WFI) Quality Water (Catalog Number 901-001-101)

Lot Number: M123006

Date of Manufacture: Jan2023

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 | 3.76 ppb |
| Total Organic Carbon (Packaged) | USP <643> | ≤ 8000 ppb | 4780 ppb |
| Physical Testing | | | |
| pH @ 25°C | USP <791> | 5.0 – 7.0 | 5.5 |
| Conductivity @ 25°C (Packaged) | USP <644>, EP 2.2.38 | ≤ 5 μS/cm | 2.824 μS/cm |
| Conductivity @ 25°C (Before Packaging) | USP <644>, EP 2.2.38 | ≤ 1.3 μS/cm | 0.077 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.

Karen Zuniga
Name

QA Associate I
Title

07FEB2023
Date