



CERTIFICATE OF ANALYSIS

GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade) (Catalog Number 901-001-011)

Lot Number: M123037

Date of Manufacture: May2023

Storage Temperature: 2°C – 30°C

Product Expiry: May2025

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 | <0.050 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 | 2.44 ppb |
| Total Organic Carbon (Packaged) | USP <643> | ≤ 8000 ppb | 3330 ppb |
| Physical Testing | | | |
| pH @ 25°C | USP <791> | 4.0 – 7.0 | 6.5 |
| Conductivity @ 25°C (Before Packaging) | USP <644>, EP 2.2.38 | ≤ 1.3 μS/cm | 0.083 μS/cm |
| Conductivity @ 25°C (Packaged) | USP <644>, EP 2.2.38 | ≤ 5 μS/cm | 1 μS/cm |
| Particulate Matter | USP <788> | | |
| ≥ 25μm in size | | ≤ 3 particles/mL | 0 particles/mL |
| ≥ 10μm in size | | ≤ 25 particles/mL | 1 particle/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.

Jequeline Wilson
Name

25 MAY 2023
Date

QA Specialist
Title