



## CERTIFICATE OF ANALYSIS

### **GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade)** **(Catalog Number 901-001-01A)**

**Lot Number:** M123061

**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 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
<b>Biological Testing</b>			
Endotoxin	USP <85>, EP 2.6.14	< 0.25 EU/mL	< 0.010 EU/mL
<b>Microbiological Testing</b>			
Sterility	USP <71>, EP 2.6.1		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
<b>Biochemistry Testing</b>			
Total Organic Carbon	USP <643>		
Before Packaging		≤ 500 ppb	3.1 ppb
Packaged		≤ 8000 ppb	2810 ppb
<b>Physical Testing</b>			
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 μS/cm	0.948 μS/cm
Particulate Matter	USP <788>		
≥ 25μm in size		≤ 3 particles/mL	0 particles/mL
≥ 10μm in size		≤ 25 particles/mL	0 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. 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