



CERTIFICATE OF ANALYSIS

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

(Catalog Number 200-888-020-KIT)

(Catalog Numbers 901-001-1LT, 901-001-021)

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.

 Julie Wilson
Name

 16 MAY 2024
Date

 QA Specialist
Title