



CERTIFICATE OF ANALYSIS

Addendum

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

Product Expiry: Jan2025

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

12 APR 2023
Date