



CERTIFICATE OF ANALYSIS

Addendum

GemPure Select WFI Quality Water (USP)

(Catalog Number 901-001-011, 901-001-101, 901-001-201)

Lot Number: M122110

Date of Manufacture: Jun2022

Storage Temperature: 2°C – 30°C

Product Expiry: Jun2024

For Cell culture, Further Manufacturing or Research use Only. Not for Direct Therapeutic 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	<0.010 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	8.7 ppb
Total Organic Carbon (Packaged)	USP <643>	≤ 8000 ppb	4140 ppb
Physical Testing			
pH @ 25°C	USP <791>	5.0 – 7.0	5.3
Conductivity @ 25°C (Packaged)	USP <644>, EP 2.2.38	≤ 5 µS/cm	1.094 µS/cm
Conductivity @ 25°C (Before Packaging)	USP <644>, EP 2.2.38	≤ 1.3 µS/cm	0.095 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