



CERTIFICATE OF ANALYSIS

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

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

07JUL2022

Date