



CERTIFICATE OF ANALYSIS

GemPure Select WFI Quality Water (USP)

(Catalog Number 901-001-021, 901-001-101, 901-001-201)

Revised September 02, 2022

Lot Number: M122106

Date of Manufacture: Jun2022

Storage Temperature: 2°C – 30°C

Product Expiry: Dec2022

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	<0.01 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	7.84 ppb
Total Organic Carbon (Packaged)	USP <643>	≤ 8000 ppb	4410 ppb
Physical Testing			
pH @ 25°C	USP <791>	5.0 – 7.0	5.9
Conductivity @ 25°C (Packaged)	USP <644>, EP 2.2.38	≤ 5 µS/cm	1.276 µS/cm
Conductivity @ 25°C (Before Packaging)	USP <644>, EP 2.2.38	≤ 1.3 µS/cm	0.09 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.

Josephine Wilson
Name

QA Specialist
Title

02SEP2022
Date