

CERTIFICATE OF ANALYSIS

GemPure Select WFI Quality Water (USP)

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

Lot Number: M122107

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	Clear and colorless
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	11.9 ppb
Total Organic Carbon (Packaged)	USP <643>	≤ 8000 ppb	3790 ppb
Physical Testing			, ,
pH @ 25°C	USP <791>	5.0 - 7.0	5.21
Conductivity @ 25°C (Packaged)	USP <644>, EP 2.2.38	≤ 5 µS/cm	1.030 μS/cm
Conductivity @ 25°C (Before Packaging)	USP <644>, EP 2.2.38	≤ 1.3 µS/cm	0.091 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.

Jugueline Wilson

QA Specialist

07 JUL 2022

Date