

CERTIFICATE OF ANALYSIS

GemPure™ Cell and Molecular Grade Water

(Catalog Number 901-004-1X6)

(Catalog Number 901-004-001)

Lot Number: M123148

Date of Manufacture: Dec2023

Storage Temperature: 2°C – 30°C

Product Expiry: Dec2025

For further Manufacturing or Research use only. Not for direct Therapeutic use.

Product Description: GemPure™ Cell and Molecular Grade Water - tested for use in cell culture and molecular biology applications.

Test	Methodology	Specification	Analysis Clear and colorless liquid	
Appearance	Visual Inspection	Clear and colorless liquid		
Biological Testing				
Endotoxin	USP <85>, EP 2.6.14	< 0.25 EU/mL	0.0131 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	USP <643>	≤ 500 ppb	2.76 ppb	
Before Packaging		≤ 8000 ppb	3920 ppb	
Packaged				
Physical Testing				
pH @ 25°C	USP <791>	4.0 - 7.0	5.58	
Conductivity @ 25°C	USP <6445>			
Before Packaging		≤ 1.3 µS/cm	1 μS/cm	
Packaged		≤ 5.0 µS/cm	1.152 μS/cm	
DNase	PCR/Fluorescence	None Detected	None Detected	
RNase	PCR/Fluorescence	None Detected	None Detected	
Protease	PCR/Fluorescence	None Detected	None Detected	

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.

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27SEP 2024

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QA Manager

Title