



CERTIFICATE OF ANALYSIS

GemPure™ Molecular Water (Catalog Number 901-007-C23)

Lot Number: M124058

Date of Manufacture: Nov2023

Storage Temperature: 2°C – 30°C

Product Expiry: Nov2025

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

Product Description: GemPure™ Molecular Water is tested to ensure the absence of DNase, RNase, and Protease activity for use in non-sterile applications.

Test	Methodology	Specification	Analysis
Biological Testing			
Endotoxin	USP<85>	< 0.25 EU/mL	<0.0105 EU/mL
Biochemistry			
Total Organic Carbon	USP <643>		
Before Packaging		≤ 500 ppb	16.6 ppb
Packaged		≤ 8000 ppb	119 ppb
Microbial Contamination	USP<61>	≤ 100 cfu/mL	<1 cfu/mL
Physical Testing			
pH @ 25°C	USP<791>	4.0 – 7.0	5.23
Conductivity @ 25°C	USP <645>		
Before Packaging		≤ 1.3 μS/cm	1 μS/cm
Packaged		≤ 5.0 μS/cm	1.186 μS/cm
DNase	Enzymatic digestion assay, visualized via Agarose Gel Electrophoresis	None Detected	None Detected
RNase	Enzymatic digestion assay, determined by visualization via denatured Agarose Gel Electrophoresis	None Detected	None Detected
Protease	Colorimetric assay, quantified against relative standard curve	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. This product was manufactured at 920 Stillwater Rd., Suite 130, West Sacramento, CA, U.S.A., which is an animal origin free facility. All final product processes/packaging were also performed at 920 Stillwater Rd., Suite 130, West Sacramento, CA, U.S.A., an animal origin free facility. This facility is ISO 13485:2016 certified.

VANESSA YOUNG
Name

05 JUN 2024
Date

QA SPECIALIST
Title