

CERTIFICATE OF ANALYSIS

GemPure™ Select Purified Water, Sterile (USP Grade)

(Catalog Number 901-005-021)

Lot Number: M123063 Date of Manufacture: Jun2023

Storage Temperature: 2°C – 30°C Product Expiry: Jun2025

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

Product Description: GemPure™ Select Purified Water, Sterile (USP Grade) meets the USP monograph for Sterile Purified Water packaged in bulk for commercial use.

Test	Methodology	Specification	Analysis
Appearance	Visual Inspection	Clear and colorless	Clear and colorless
		liquid	liquid
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	6.28 ppb
Total Organic Carbon (Packaged)	USP <643>	≤ 8000 ppb	4180 ppb
Physical Testing			• • • • • • • • • • • • • • • • • • • •
Conductivity @ 25°C (Before Packaging)	USP <644>, EP 2.2.38	≤ 1.3 µS/cm	0.09 μS/cm
Conductivity @ 25°C (Packaged)	USP <644>, EP 2.2.38	≤ 5.0 μS/cm	1.570 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.

VANESSA YOUNG	14JUL2023	
Name	Date	
QA ASSOCIATE 11		
Title		