

CERTIFICATE OF ANALYSIS

GemPure™ Select Purified Water, Sterile (USP Grade)

(Catalog Number 901-005-001)

Lot Number: M123073

Date of Manufacture: Jul2023

Storage Temperature: 2°C - 30°C

Product Expiry: Jul2025

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	2.49 ppb
Total Organic Carbon (Packaged)	USP <643>	≤ 8000 ppb	5360 ppb
Physical Testing			• • •
Conductivity @ 25°C (Before Packaging)	USP <644>, EP 2.2.38	≤ 1.3 µS/cm	0.091 μS/cm
Conductivity @ 25°C (Packaged)	USP <644>, EP 2.2.38	≤ 5.0 µS/cm	1.322 µS/cm
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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.

Name Ospecialist