



CERTIFICATE OF ANALYSIS

GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade) **(Catalog Number 901-001-203, 901-001-1LT)**

Lot Number: M124009

Date of Manufacture: Jan2024

Storage Temperature: 2°C – 30°C

Product Expiry: Jan2026

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

Product Description: GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade) meets the USP monograph for Water for Injection packaged in bulk for commercial use.

Test	Methodology	Specification	Analysis
Appearance	Visual Inspection	Clear and colorless liquid	Clear and colorless liquid
Biological Testing			
Endotoxin	USP <85>, EP 2.6.14	< 0.25 EU/mL	<0.0100 EU/mL
Microbiological Testing			
Sterility	USP <71>, EP 2.6.1		
Bacteria		No Growth	No Growth
Fungi		No Growth	No Growth
Biochemistry Testing			
Total Organic Carbon	USP <643>		
Before Packaging		≤ 500 ppb	5.21 ppb
Packaged		≤ 8000 ppb	1340 ppb
Physical Testing			
pH @ 25°C	USP <791>	4.0 – 7.0	5.55
Conductivity @ 25°C	USP <645>		
Before Packaging		≤ 1.3 µS/cm	1 µS/cm
Packaged		≤ 5 µS/cm	2.260 µS/cm
Particulate Matter	USP <788>		
≥ 25µm in size		≤ 3 particles/mL	0 particles/mL
≥ 10µm in size		≤ 25 particles/mL	1 particles/mL

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.

Megha Khatali
Name

08 MAY 2024
Date

QA Manager
Title