CERTIFICATE OF ANALYSIS

GemPure™ Select Water for Irrigation (WFIr) Quality Water (USP Grade)

(Catalog Number 901-003-1X6)

(Catalog Number 901-003-001)

Lot Number: M426040 **Date of Manufacture:** Jun2025

Storage Temperature: 2°C – 30°C **Product Expiry**: Jun2027

For further manufacturing or research use only. Not for direct therapeutic use.

Product Description: GemPure™ Select Water for Irrigation (WFIr) Quality Water (USP Grade) meets the USP monograph for Sterile Water for Irrigation 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	<0.0050 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	30 ppb
Packaged		≤ 8000 ppb	144 ppb
Physical Testing			
pH @ 25°C	USP <791>	4.0 – 7.0	6.4
Conductivity @ 25°C	USP <645>		
Before Packaging		≤ 1.3 µS/cm	1.1 µS/cm
Packaged		≤ 5.0 µS/cm	2 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. This product was manufactured at an animal origin free facility. All final product processes/packaging were also performed at an animal origin free facility. This facility is ISO 13485:2016 certified.

Alejandra Peña
Name

16Nov2026
Date

QA Associate II
Title