CERTIFICATE OF ANALYSIS

GemPure™ Plus Water for Injection (WFI) Quality Water

(USP/EP/JP Grade)

(Catalog Number 901-002-021)

Lot Number: M123119

Date of Manufacture: Oct2023 **Product Expiry:** Oct2025

Storage Temperature: 2°C – 30°C

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

Product Description: *GemPure™ Plus Water for Injection (WFI) Quality Water (USP/EP/JP Grade) meets the USP/EP/JP 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	<0.010 EU/mL
Microbiological Testing			
Sterility	USP <71>, EP 2.6.1		
Bacteria		No growth	No growth
Fungi		No growth	No growth
Biochemistry Testing			
Acidity or Alkalinity	EP	No change in appearance	No change in appearance
Ammonium	EP	≤0.2 ppm	<0.2 ppm
Calcium and Magnesium	EP	Blue color produced	Blue color produced
Chlorides	EP	No change in appearance	No change in appearance
Extractable Volume	JP<6.05>	Volume is not less than the nominal volume	Volume is not less than the nominal volume
Foreign Insoluble Matter	JP<6.06>	See Particulate Matter	Pass
Heavy Metals	EP 2.4.27	≤0.1 ppm	<0.1 ppm
Nitrates	EP	≤0.2 ppm	<0.2 ppm
Oxidizable Substances	USP/EP	Pink color does not completely disappear	Pink color does not completely disappear
Particulate Matter	USP <788>, EP 2.9.19		
≥ 25µm in size		≤ 3 particles/mL	0 particles/mL
≥ 10µm in size		≤ 25 particles/mL	0 particles/mL
Purity	JP	Pass	Pass
Residue on Evaporation	EP	≤3 mg (0.003%)	1 mg (0.001%)
Sulfates	EP	No change in appearance	No change in appearance
Total Organic Carbon	USP <643>		
Before Packaging		≤ 500 ppb	2.06 ppb
Packaged		≤ 8000 ppb	701 ppb

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Test	Methodology	Specification	Analysis
Physical Testing			
pH @ 25°C	USP <791>	4.0 – 7.0	5.4
Conductivity @ 25°C	USP <645>		
Before Packaging		≤ 1.3 µS/cm	1 µS/cm
Packaged		≤ 5 µS/cm	1.550 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 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

02may2024
Date

QA SPECIALIST
Title