



CERTIFICATE OF ANALYSIS

GemPure™ Plus Water for Injection (WFI) Quality Water

(USP/EP/JP Grade)

(Catalog Number 901-002-004)

Lot Number: M123064

Date of Manufacture: Jun2023

Product Expiry: Jun2025

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	0.021 EU/mL
Microbiological Testing			
Sterility	USP <71>, EP 2.6.1		
Bacteria		No growth	No growth
Fungi		No growth	No growth
Biochemistry			
Acidity or Alkalinity	EP	No change in appearance	No change in appearance
Ammonium	EP	≤0.2 ppm	<0.2 ppm
Calcium and Magnesium Chlorides	EP	Blue color produced	Blue color produced
Extractable Volume	JP<6.05>	No change in appearance	No change in appearance
Foreign Insoluble Matter	JP<6.06>	Volume is not less than the nominal volume	Volume is not less than the nominal volume
Heavy Metals	EP 2.4.27	See Particulate Matter	Pass
Nitrates	EP	≤0.1 ppm	<0.1 ppm
Oxidizable Substances	USP/EP	≤0.2 ppm	<0.2 ppm
Particulate Matter	USP <788>, EP 2.9.19	Pink color does not completely disappear	Pink color does not completely disappear
≥ 25µm in size		completely disappear	completely disappear
≥ 10µm in size		≤ 3 particles/mL	0 particles/mL
Purity	JP	≤ 25 particles/mL	0 particles/mL
Residue on Evaporation	EP	Pass	Pass
Sulfates	EP	≤3 mg (0.003%)	0.9 mg (0.0009%)
Total Organic Carbon	USP <643>	No change in appearance	No change in appearance
Before Packaging			
Packaged		≤ 500 ppb	1.72 ppb
		≤ 8000 ppb	2940 ppb



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Test	Methodology	Specification	Analysis
Physical Testing			
pH @ 25°C	USP <791>	4.0 – 7.0	5.6
Conductivity @ 25°C	USP <644>, EP 2.2.38		
Before Packaging		≤ 1.3 µS/cm	0.09 µS/cm
Packaged		≤ 5 µS/cm	1.342 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
Name

17 JUL 2023
Date

QA ASSOCIATE II
Title