



CERTIFICATE OF ANALYSIS

Addendum

GemPure™ Select Water for Injection (WFI) Quality Water (USP Grade)

(Catalog Number 901-001-011, 901-001-101, 901-001-201)

Lot Number: M122110

Date of Manufacture: Jun2022

Storage Temperature: 2°C – 30°C

Product Expiry: Jun2024

For Cell Culture, 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	<0.010 EU/mL
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	8.7 ppb
Total Organic Carbon (Packaged)	USP <643>	≤ 8000 ppb	4140 ppb
Physical Testing			
pH @ 25°C	USP <791>	4.0 – 7.0	5.3
Conductivity @ 25°C (Before Packaging)	USP <644>, EP 2.2.38	≤ 1.3 µS/cm	0.095 µS/cm
Conductivity @ 25°C (Packaged)	USP <644>, EP 2.2.38	≤ 5 µS/cm	1.094 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

21 APR 2023

Date

QA ASSOCIATE II

Title