



Certificate of Analysis

Sterile Water For Injection, USP

Product Code	: 918520	Manufacturing Date	: 12 Jul 2023
Batch Number	: 6032768	Expiration Date	: Jul 2026

Test	Method	Specification	Result
Color of Solution	03-08-07-0057		
Color of Solution		Compares To Standard	Complies
dAPHA		NMT 50 dAPHA	2
Total Organic Carbon	10-08-03-7299		
Total Organic Carbon			0.67 ppm
Total Organic Carbon- USP		Meets the USP requirements	Meets Specification
Visual Inspection	10-08-05-6005		
Description		Solution in a 20cc Plastic Vial	Solution in a 20cc Plastic Vial
Clarity		Clear	Clear
Particulate Matter		Essentially free from visible particulate matter	Meets Specification
Color		Colorless	Colorless
Volume Check	03-08-03-0002	NLT 20 mL	NLT 20 mL
Identification	Add 1 drop of product to 5.0 mL of Karl Fisher ® reagent to a test tube	Solution becomes light yellow	Meets Specification
Conductivity	03-08-07-0054	NMT 5 µS/cm	1 µS/cm
Particulate Matter In Injections - Beginning	03-10-02-0002		
Particulate Matter >= 10 µm		For particles ≥ 10 µm: NMT 6,000 particles per container	59 Particles/Container
Particulate Matter >= 25 µm		For particles ≥ 25 µm: NMT 600 particles per container	0 Particles/Container
Particulate Matter In Injections - Middle	03-10-02-0002		
Particulate Matter >= 10 µm		For particles ≥ 10 µm: NMT 6,000 particles per container	45 Particles/Container
Particulate Matter >= 25 µm		For particles ≥ 25 µm: NMT 600 particles per container	0 Particles/Container
Particulate Matter In Injections - End	03-10-02-0002		
Particulate Matter >= 10 µm		For particles ≥ 10 µm: NMT 6,000 particles per container	72 Particles/Container
Particulate Matter >= 25 µm		For particles ≥ 25 µm: NMT 600 particles per container	0 Particles/Container
Other Requirements:	USP <1>		
Sterility- FP Spec		Meets requirements of USP <1>	Complies
Volume In Container- FP Spec		Meets requirements of USP <1>	Complies
Foreign Matter/Particulate Matter- 100% Visual Inspection		Meets requirements	Complies