

Certificate Of Analysis



Date of Release: 15-AUG-19

Name: WATER, STERILE, Cell Culture Tested (WFI Quality)

Item No: 4.86505 all size codes

Lot / Batch No: 21319001

Country of Origin: USA

Characteristic	Requirement		Results	Units
	Min.	Max.		
Water Conductivity (packaged water)			Passes Test (2 uS/cm at 25°C)	
Water Conductivity (prior to packaging, stage 1)			Passes Test (0.32 uS/cm at 85°C)	
DNase			None Detected	
Expiration Date			07-2022	
Oxidizable Substances			Passes Test (solution remains faintly pink)	
Plating Efficiency			Passes Test	
Protease			None Detected	
RNase			None Detected	
Particulate Matter in Injections		25 Particles per mL that are $\geq 10\mu\text{m}$ in size	0.7	Particles per mL
Particulate Matter in Injections		3 Particles per mL that are $\geq 25\mu\text{m}$ in size	0.07	Particles per mL
TOC (prior to packaging)		500	25	ppb
Sterility by USP			Passes Test	
Bacterial Endotoxin		0.025	< 0.0010	EU/mL

Oxidizable Substances tested in accordance with current USP monograph for "Sterile Purified Water".
Sterility tested by membrane filtration technique in accordance with current USP monograph chapter <71>.
Water Conductivity <645> and TOC <643> tested in accordance with current USP monograph.
Particulate Matter in Injections tested in accordance with current USP monograph chapter <788>.

For manufacturing or research use only. Not for human or animal injection, diagnostic or therapeutic use.

Joe Schoellkopff

Quality Control Manager

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