FRESENIUS KABI

Fresenius Kabi USA
3159 Staley Road
Grand Island, New York 14072

+01 (716) 773-0800

Certificate of Analysis

Sterile Water For Injection, USP

Product Code	: 18505	**Manufacturing Date**	: 06 May 2018
Batch Number	: 6016834	**Expiration Date**	: May 2021

Test	Method	Specification	Result
Visual Inspection	10-08-05-6005		
Appearance		Clear solution in a vial.	Complies
Particulate Matter		Essentially free from visible particulate matter	Complies
Clarity		Clear	Complies
Color		Colorless	Complies
Container/Closure		Container is intact	Complies
Conductivity	USP	NMT 25 µS/cm	4 µS/cm
Oxidizable Substances	03-08-01-0042	The pink color does not completely disappear	Complies
Volume in Container (5 mL Label Claim)	03-08-03-0002	NLT 5 mL/vial	Complies
Particulate Matter in Injections - Beginning	03-10-02-0002		
Particles >= 10 µm		NMT 6000 particles per container.	54 Particles/Container
Particles >= 25 µm		NMT 600 particles per container.	1 Particles/Container
Particulate Matter in Injections - Middle	03-10-02-0002		
Particles >= 10 µm		NMT 6000 particles per container.	42 Particles/Container
Particles >= 25 µm		NMT 600 particles per container.	0 Particles/Container
Particulate Matter in Injections - End	03-10-02-0002		
Particles >= 10 µm		NMT 6000 particles per container.	39 Particles/Container
Particles >= 25 µm		NMT 600 particles per container.	0 Particles/Container
Sterility Test	03-10-07-0001	Sterile	Complies
Bacterial Endotoxins Test	03-10-08-0005	<0.25 EU per mL	<0.05 EU/mL
Other Requirements	USP <1>		
Sterility- FP Spec		Meets the requirements under Injection USP <1>	Complies
Foreign Matter		Meets the requirements under Injection USP <1>	Complies
Particulate Matter- FP Spec		Meets the requirements under Injection USP <1>	Complies
Vehicles and Added Substances		Vehicles and Added Substances are specified per approved master formula.	Complies
Labels and Labeling		Labels and Labeling are specified per approved labeling material represented on batch record pages R6, R8 and R9	Complies
Containers and Closures		Containers, including closures, are defined by approved master component specifications.	Complies
Packaging and Storage		Packaging and Storage are defined by approved product material.	Complies
Labeling	USP	Meets specification	Complies

FRESENIUS KABI

Fresenius Kabi USA
3159 Staley Road
Grand Island, New York 14072

+01 (716) 773-0800

Certificate of Analysis

Sterile Water For Injection, USP

Product Code	: 18505	**Manufacturing Date**	: 06 May 2018
Batch Number	: 6016834	**Expiration Date**	: May 2021

This finished drug product complies to the USP <467> General Chapter for Residual Solvents per Option 1

This is an electronic signature

QC Approval By	: Michelle Webb Product Release Specialist	**QC Approval Date**	: 30 May 2018