

Certificate of Analysis**Product: STERILE WATER FOR IRRIGATION, USP - 250 ML****Lot #: G127803****Code: 2F7112****Expiry: MAR 2020****Manufactured Date: 03/30/2017****Sterilization Date: 03/30/2017****Mixing Specification: 03-15-53-216****Issue Date: 02/26/2015**

TEST NUMBER	TEST NAME	LIMIT	RESULT
11-20-15-001	Oxidizable Substances	Pass	Pass
11-21-16-003	pH at 25 deg. C	5.0 - 7.0	5.5
11-22-03-007	Conductivity Determination of Water (USP/EP)	NMT 5 uS/cm	1 uS/cm
20-03-07-006	Particle Analysis - Large Volume (Instrumental)		
	Particles >= 10 micron	NMT 25 particles/mL >=10 microns	1 ct/mL
	Particles >= 25 micron	NMT 3 particles/mL >=25 microns	0 ct/mL
13-01-10-313	Bacterial Endotoxin	< 0.25 EU/mL	< 0.02 EU/mL
14-04-01-120	Sterility	Pass Parametric Release	Pass
PARAMETRIC RELEASE IN ACCORDANCE WITH U.S. FDA REQUIREMENTS			

THIS PRODUCT WAS MANUFACTURED ACCORDING TO CURRENT GMP,
FULLFILLS THE REQUIREMENTS OF THE MASTER PRODUCTION DOCUMENT AND TESTED TO USP COMPLIANCE

 4-3-17

Prepared By/Date

 4-5-17

Quality Management Approval /Date

Ellen Soliz