

Certificate of Analysis

Product: STERILE WATER FOR IRRIGATION, USP - 1000 ML

Lot #: G119248
Code: 2F7114
Expiry: SEP 2018

Manufactured Date: 09/10/2015
Sterilization Date: 09/10/2015
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	5.6
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	0 ct/mL
	Particles >= 25 micron	NMT 3 particles/mL >=25 microns	0 ct/mL
13-01-V	Bacterial Endotoxin	< 0.25 EU/mL = Pass	Pass
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

E. Soliz 9-14-15
Prepared By/Date

Ellen Soliz

Twila Proctor 9-15-15
Quality Management Approval /Date

Twila Proctor