

Certificate of Analysis

Product: STERILE WATER FOR IRRIGATION, USP - 1000 ML

Lot #: G110817

Code: 2F7114

Expiry: JAN 2017

Manufactured Date: 01/08/2014

Sterilization Date: 01/08/2014

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	5.7
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	2 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 1-10-14
Prepared By/Date

UPorter 1-10-14
Quality Management Approval /Date

ELLEN SOLIZ