

Certificate of Analysis

Product: STERILE WATER FOR IRRIGATION, USP - 1000 ML

Lot #: G100768

Code: 2F7114

Expiry: FEB/2015

Manufactured Date: 02/28/2012

Sterilization Date: 02/28/2012

TEST	LIMIT	RESULT
Conductivity Determination of Water (USP/EP)	NMT 5 uS/cm	2 uS/cm
Oxidizable Substances	Pass	Pass
pH at 25 deg. C	5.0 - 7.0	5.6
Particle Analysis	NMT 25 particles/mL $\geq$ 10 microns	0
Particle Analysis	NMT 3 particles/mL $\geq$ 25 microns	0
Bacterial Endotoxin	< 0.25 Eu/mL = Pass	Pass
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 3.1.12
Prepared By/Date

ELLEN SOLIZ

^{WPD}
Proctor 3/1/12
Quality Management Approval /Date

Twila Proctor

Certificate of Analysis**Product: 0.9% SODIUM CHLORIDE IRRIGATING SOLUTION****Lot #: G100792****Code: 2F7124****Expiry: FEB/2015****Manufactured Date: 02/27/2012****Sterilization Date: 02/27/2012**

TEST	LIMIT	RESULT
NaCl (g/L)	8.55 - 9.45 g/L	9.02 g/L
Sodium ID- Flame	Positive	Positive
Sodium ID- USP	Positive	Positive
pH at 25 deg. C	4.5 - 7.0	5.8
Particle Analysis	NMT 25 particles/mL $\geq$ 10 microns	0
Particle Analysis	NMT 3 particles/mL $\geq$ 25 microns	0
Bacterial Endotoxin	< 0.25 Eu/mL = Pass	Pass
Sterility	Pass Parametric Release	Pass

PARAMETRIC RELEASE IN ACCORDANCE WITH US. FDA REQUIREMENTS

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

ELLEN SOLIZ 2-29-12
Prepared By/Date**ELLEN SOLIZ**Twila Proctor 2-29-12
Quality Management Approval /Date**Twila Proctor**