

Certificate of Analysis

Product: 0.9% SODIUM CHLORIDE IRRIGATING SOLUTION

Lot #: G101907
Code: 2F7124
Expiry: MAY/2015

Manufactured Date: 05/08/2012
Sterilization Date: 05/08/2012

TEST	LIMIT	RESULT
NaCl (g/L)	8.55 - 9.45 g/L	8.99 g/L
Sodium ID- Flame	Positive	Positive
Sodium ID- USP	Positive	Positive
pH at 25 deg. C	4.5 - 7.0	5.5
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.

E. Soliz 5-10-12
Prepared By/Date

ELLEN SOLIZ

Twila Proctor 5/10/12
Quality Management Approval /Date

Twila Proctor