

Certificate of Analysis

Product: 0.9% SODIUM CHLORIDE IRRIGATING SOLUTION

Lot #: G114538
Code: 2F7124
Expiry: SEP 2017

Manufactured Date: 09/18/2014
Sterilization Date: 09/18/2014

TEST NUMBER	TEST NAME	LIMIT	RESULT
11-07-19-001	NaCl (g/L)	8.55 - 9.45 g/L	8.93 g/L
11-20-19-006	Sodium ID- USP	Positive	Positive
11-20-19-007	Sodium ID- Flame	Positive	Positive
11-21-16-003	pH at 25 deg. C	4.5 - 7.0	5.8
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	< 0.5 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 9.24.14
Prepared By/Date

ELLEN SOLIZ

T. Proctor 9-24-14
Quality Management Approval /Date
T. Proctor