

Certificate of Analysis**Product: 0.9% SODIUM CHLORIDE IRRIGATING SOLUTION****Lot #: G127290**
Code: 2F7124
Expiry: FEB 2020**Manufactured Date: 02/16/2017**
Sterilization Date: 02/16/2017
Mixing Specification: 03-15-19-156
Issue Date: 07/02/2002

TEST NUMBER	TEST NAME	LIMIT	RESULT
11-07-19-001	NaCl (g/L)	8.55 - 9.45 g/L	8.98 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	5.6
20-03-07-006	Particle Analysis - Large Volume (Instrumental)		
	Particles >= 10 micron	NMT 25 particles/mL >=10 microns	1 ct/mL
	Particles >= 25 micron	NMT 3 particles/mL >=25 microns	0 ct/mL
13-01-10-313	Bacterial Endotoxin	0.5 EU/mL	< 0.01 EU/mL
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

 2-20-17
Prepared By/Date

Ellen Soliz

 2-23-17
Quality Management Approval /Date

