



MEDICAL PRODUCTS - CLEVELAND FACILITY  
911 North Davis Avenue, Cleveland, MS 38732, Phone: 662.843.9421, Fax: 662.846.5987

### Certificate of Analysis

**Product:** 0.9% SODIUM CHLORIDE IRRIGATING SOLUTION

**Lot #:** G125872

**Code:** 2F7124

**Expiry:** NOV 2019

**Manufactured Date:** 11/19/2016

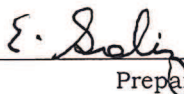
**Sterilization Date:** 11/19/2016

**Mixing Specification:** 03-15-19-156

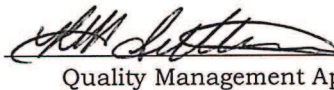
**Issue Date:** 07/02/2002

| TEST NUMBER                                                 | TEST NAME                                       | LIMIT                            | RESULT       |
|-------------------------------------------------------------|-------------------------------------------------|----------------------------------|--------------|
| 11-07-19-001                                                | NaCl (g/L)                                      | 8.55 - 9.45 g/L                  | 9.00 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 | 0 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

 11-17-16  
Prepared By/Date

Ellen Soliz

 11-18-16  
Quality Management Approval /Date