

BAXTER CLEVELAND PRODUCT CERTIFICATION

911 North Davis
Cleveland, MS 38732
(2F7112 / 2F7113 / 2F7114 / 2F7115)

CODE <u>2F7114</u>	BATCH <u>M139809</u>	MFG. DATE <u>5-26-19</u>	STERILIZATION DATE <u>5-26-19</u>
PLANT OF MANUFACTURE CLEVELAND, MS		EXPIRY DATE <u>May 2022</u>	
DESCRIPTION			

Sterile Water for Irrigation, USP

TEST	LIMITS	SAMPLE RESULTS	DATE PASSED
BACTERIAL ENDOTOXIN (PYROGEN)	CONTROL LIMIT (Eu/mL)		
13-01-10-313	<0.25 EU/ml = Pass	EU/mL 20.0200	5-28-19
STERILITY PARAMETRIC RELEASE	PASS	PASSED	5-26-19
PARTICLE ANALYSIS	≥ 10 um/mL NMT 25	part/mL 1	
20-03-07-006	≥ 25 um/mL NMT 3	part/mL 0	5-28-19

PARAMETRIC RELEASE IN ACCORDANCE WITH U.S. FDA REQUIREMENTS

CHEMICAL RESULTS 3-15-53-216 ISSUE DATE 2-26-15

REFERENCE	TEST	LIMITS	RESULT
11-21-16-003	pH at 25°C	5.0-7.0	5.5
11-20-15-001	Oxidizable Substances	Pass	Pass
11-22-03-007	Conductivity	NMT 5µs/cm @25±1°C	1.0 µs/cm

THIS LOT HAS BEEN PRODUCED IN ACCORDANCE WITH PROCEDURES IN THE MASTER PRODUCTION DOCUMENT.
THIS LOT HAS BEEN PRODUCED IN ACCORDANCE WITH CURRENT USP REQUIREMENTS.

DATE BATCH RELEASED 5-31-19PREPARED BY/DATE E. Soliz 6-3-19QUALITY MANAGEMENT SUPERVISOR (JW) 6/3/19