

BAXTER CLEVELAND PRODUCT CERTIFICATION
911 North Davis
Cleveland, MS 38732
(2F7112 / 2F7113 / 2F7114 / 2F7115)

CODE <u>2F7113</u>	BATCH <u>2139861</u>	MFG. DATE <u>5-28-19</u>	STERILIZATION DATE <u>5-28-19</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 <u>4.025</u>	<u>5-30-19</u>
STERILITY PARAMETRIC RELEASE	PASS	PASSED	<u>5-28-19</u>
PARTICLE ANALYSIS 20-03-07-006	≥ 10 um/mL NMT 25	part/mL <u>1</u>	<u>5-29-19</u>
	≥ 25 um/mL NMT 3	part/mL <u>0</u>	

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	<u>5.6</u>
11-20-15-001	Oxidizable Substances	Pass	<u>Pass</u>
11-22-03-007	Conductivity	NMT 5µs/cm @25±1°C	<u>1.1</u> 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 6-3-19PREPARED BY/DATE E. Solis 6-3-19QUALITY MANAGEMENT SUPERVISOR [Signature] 6/3/19