

Certificate of Analysis

Product Name: Azer Prefilled Saline

Description: Prefilled saline vial, 10mL vial with 3mL fill, no label, non-sterile, 1000/case

Product No.: ES45045-BLK-NS

Lot. No.: 27733

Date of Manufacture: 2022-01-25

Expiration Date: 2023-01-10

Product Specifications:

Ingredients: Sodium Chloride, USP Grade
Deionized Water, NCCLS Type I Reagent Grade

Packaging: Product undergoes a two-phase sub-micron filtration process as well as UV Sterilization before filling process begins.
Packaged in 10 mL vials (3 mL fill)

Materials:

	<u>Part No.</u>	<u>Lot No.</u>	<u>Exp. Date</u>
Container/Cap:	4004-1547	200849	N/A
		200848	
		200847	
Chemical:	ES1244-1000	2A27532	2023-07-10
		2A27727	2023-07-24
		2A27812	2023-07-31
		2B27915	2023-08-07

QC Testing:

LOT NUMBER: 2A27532			
ATTRIBUTE	SPECIFICATION	RESULTS	PASS / FAIL
Appearance	Clear, colorless, no observable particulate	Pass	PASS
pH	6.5 - 7.0	6.52	PASS
Assay	0.85% to 0.90%	0.88%	PASS
TAMC	< 10 CFU/ml	< 1 CFU/ml	PASS
TYMC	< 10 CFU/ml	<1 CFU/ml	PASS

LOT NUMBER: 2A27727

ATTRIBUTE	SPECIFICATION	RESULTS	PASS / FAIL
Appearance	Clear, colorless, no observable particulate	Pass	PASS
pH	6.5 - 7.0	6.74	PASS
Assay	0.85% to 0.90%	0.88%	PASS
TAMC	< 10 CFU/ml	< 1 CFU/ml	PASS
TYMC	< 10 CFU/ml	<1 CFU/ml	PASS
LOT NUMBER: 2A27812			
ATTRIBUTE	SPECIFICATION	RESULTS	PASS / FAIL
Appearance	Clear, colorless, no observable particulate	Pass	PASS
pH	6.5 - 7.0	6.73	PASS
Assay	0.85% to 0.90%	0.88%	PASS
TAMC	< 10 CFU/ml	< 1 CFU/ml	PASS
TYMC	< 10 CFU/ml	<1 CFU/ml	PASS
LOT NUMBER: 2B27915			
ATTRIBUTE	SPECIFICATION	RESULTS	PASS / FAIL
Appearance	Clear, colorless, no observable particulate	Pass	PASS
pH	6.5 - 7.0	6.85	PASS
Assay	0.85% to 0.90%	0.88%	PASS
TAMC	< 10 CFU/ml	< 1 CFU/ml	PASS
TYMC	< 10 CFU/ml	<1 CFU/ml	PASS

Country of Origin: United States of America

Latex Free: This product contains no latex

Created By:

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