

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)

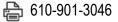
Materials:

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

QC Testing:

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

LOT NUMBER: 2A27727





ATTRIBUTE	SPECIFICATION	RESULTS	PASS / FAIL		
Appearance	Clear, colorless, no observable particulate	Pass	PASS		
рН	6.5 - 7.0	6.74	PASS		
Assay	0.85% to 0.90%	0.88%	PASS		
ТАМС	< 10 CFU/ml	< 1 CFU/ml	PASS		
ТҮМС	< 10 CFU/ml	<1 CFU/ml	PASS		
	LOT NUMBER: 2A2781	2			
ATTRIBUTE	SPECIFICATION	RESULTS	PASS / FAIL		
Appearance	Clear, colorless, no observable particulate	Pass	PASS		
рН	6.5 - 7.0	6.73	PASS		
Assay	0.85% to 0.90%	0.88%	PASS		
ТАМС	< 10 CFU/ml	< 1 CFU/ml	PASS		
ТҮМС	< 10 CFU/ml	<1 CFU/ml	PASS		
	LOT NUMBER: 2B27915				
ATTRIBUTE	SPECIFICATION	RESULTS	PASS / FAIL		
Appearance	Clear, colorless, no observable particulate	Pass	PASS		
рН	6.5 - 7.0	6.85	PASS		
Assay	0.85% to 0.90%	0.88%	PASS		
ТАМС	< 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:

James Osborn Quality Assurance Associate