

## QUALITY CERTIFICATE Certificate of Analysis (CoA)

**Ref:** 3990125 (Former: 14366SNS) - Syringe NaCl 0,9%, Luer Lock 10 ml (5ml fill) SNS

**Batch:** 2411081

**Expiry date:** 2027-07

The following data are related to the sodium chloride (NaCl) 0,9% solution:

Tests:	Specifications:	Results per batch:		
		2408026	2408027	2409129
pH	4.5 – 7.0	6.7	6.8	6.2
Iron	<1 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm
Heavy metals	<1 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm
Bacterial Endotoxins	< 0.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL
NaCl Concentration	0.86-0.95 g/100mL	0.94 g/100ml	0.94 g/100ml	0.94 g/100ml

Tests:	Specifications:	Results per batch:	
		2407132	2407135
pH	4.5 – 7.0	6.6	6.3
Iron	<1 ppm	0.0432 ppm	<0.04 ppm
Heavy metals	<1 ppm	0.0536 ppm	<0.04 ppm
Bacterial Endotoxins	< 0.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL
NaCl Concentration	0.86-0.95 g/100mL	0.92 g/100ml	0.92 g/100ml

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:			
		2409046	2410005	2407265	2407281
Clarity	Transparent	Complies	Complies	Complies	Complies
Colour	Colourless	Complies	Complies	Complies	Complies
Extractable volume	≥ 5.00 mL	5.08 mL	5.01 mL	5.11 mL	5.00 mL

The following data are related to the prefilled syringes final release testing:

Tests:	Specifications:	Result
Bacterial Endotoxins	< 0.5 EU/mL	<0.5 EU/mL

**Sterisets Manufacturing S.A.**

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The above mentioned product prefilled syringe NaCl 0,9% has been manufactured by Sterisets Manufacturing S.A. and complies with the specifications for batch release according to IMP 214 and IMP 075.

**Quality Department**

*Joana Pinto*

23/12/2024