

QUALITY CERTIFICATE

Certificate of Analysis (CoA)

Ref: 3990110 (Former: 14363SNS)- Syringe NaCl 0,9%, Luer Lock, 10 ml SNS

Batch: 2412068

Expiry date: 2027-10

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

Tests:	Specifications:	Results per batch:			
		2410004	2410039	2410042-1	2410089-1
pH	4.5 – 7.0	6.3	6.3	6.1	6.7
Iron	<1 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm	<0.2 ppm
Heavy metals	<1 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm	<0.2 ppm
Bacterial Endotoxins	< 0.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL
NaCl Concentration	0.86-0.95 g/100mL	0.91 g/ 100ml	0.91 g/ 100ml	0.93 g/ 100ml	0.93 g/ 100ml

Tests:	Specifications:	Results per batch:			
		2410043-1	2410095-1	2410096-1	2410095-2
pH	4.5 – 7.0	6.1	6.3	5.9	6.2
Iron	<1 ppm	<0.04 ppm	<0.2 ppm	<0.2 ppm	<0.2 ppm
Heavy metals	<1 ppm	0.058 ppm	<0.2 ppm	<0.2 ppm	<0.2 ppm
Bacterial Endotoxins	< 0.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL
NaCl Concentration	0.86-0.95 g/100mL	0.92 g/ 100ml	0.93 g/ 100ml	0.94 g/ 100ml	0.94 g/ 100ml

Tests:	Specifications:	Results per batch:		
		2410170-2	2410171-1	2410175-1
pH	4.5 – 7.0	6.0	6.0	5.9
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	0.91 g/ 100ml	0.91 g/ 100ml	0.94 g/ 100ml

Sterisets Manufacturing S.A.

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The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:			
		2410131	2410211	2410244	2411040
Clarity	Transparent	Complies	Complies	Complies	Complies
Colour	Colourless	Complies	Complies	Complies	Complies
Extractable volume	≥ 10.00 mL	10.18 mL	10.16 mL	10.15 mL	10.10 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

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

23/01/2025

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