

QUALITY CERTIFICATE Certificate of Analysis (CoA)

Ref: 3020010 - Syringe Water with NaCl 0,9%, Luer Lock, 10 ml – fill 10 ml

Batch: 2501020

Expiry date: 2027-10

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

Tests:	Specifications:	Results per batch:			
		2410041-1	2410041-2	2410042-1	2410089-1
pH	4.5 – 7.0	6.3	6.2	6.1	6.7
Iron	<1 ppm	<0.2 ppm	<0.04 ppm	<0.04 ppm	<0.2 ppm
Heavy metals	<1 ppm	<0.2 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	0.90 g/ 100ml	0.92 g/ 100ml	0.93 g/ 100ml	0.93 g/ 100ml

Tests:	Specifications:	Results per batch:			
		2410089-2	2410095-1	2410171-2	2410172-1
pH	4.5 – 7.0	6.4	6.3	6.0	6.0
Iron	<1 ppm	<0.04 ppm	<0.2 ppm	<0.04 ppm	<0.04 ppm
Heavy metals	<1 ppm	<0.04 ppm	<0.2 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	<0.5 EU/mL
NaCl Concentration	0.86-0.95 g/100mL	0.94 g/ 100ml	0.93 g/ 100ml	0.94 g/ 100ml	0.91 g/ 100ml

Tests:	Specifications:	Results per batch:			
		2410172-2	2410174-1	2410174-2	2410096-1
pH	4.5 – 7.0	6.0	5.9	5.9	5.9
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	0.94 g/ 100ml	0.94 g/ 100ml	0.89 g/ 100ml	0.94 g/ 100ml

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Tests:	Specifications:	Results per batch:	
		2410096-2	2410100-1
pH	4.5 – 7.0	5.9	6.1
Iron	<1 ppm	<0.2 ppm	<0.04 ppm
Heavy metals	<1 ppm	<0.2 ppm	<0.4 ppm
Bacterial Endotoxins	< 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

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:				
		2410138	2410210	2410245	2411047	2411066
Clarity	Transparent	Complies	Complies	Complies	Complies	Complies
Colour	Colourless	Complies	Complies	Complies	Complies	Complies
Extractable volume	≥ 10.00 mL	10.10 mL	10.14 mL	10.12 mL	10.07 mL	10.14 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

31/01/2025