

## QUALITY CERTIFICATE Certificate of Analysis (CoA)

**Ref:** 3010010 - Syringe Water with NaCl 0,9%, Luer Lock, 10 ml-Fill 10 ml

**Batch:** 2411107

**Expiry date:** 2027-09

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

Tests:	Specifications:	Results per batch:		
		2409055	2409056	2409107
pH	4.5 – 7.0	6.6	7.0	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	0.93 g/ 100ml	0.91 g/ 100ml	0.93 g/ 100ml

Tests:	Specifications:	Results per batch:		
		2409128	2409100	2409101
pH	4.5 – 7.0	6.2	6.3	6.3
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	0.93 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:		
		2409186	2410007	2410033
Clarity	Transparent	Complies	Complies	Complies
Colour	Colourless	Complies	Complies	Complies
Extractable volume	≥ 10.00 mL	10.08 mL	10.16 mL	10.19 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*

19/12/2024