

QUALITY CERTIFICATE Certificate of Analysis (CoA)

Ref: 3990210 (Former:14363S) - Syringe NaCl 0,9% Luer Lock 10 ml

Batch: 2411080

Expiry date: 2027-09

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

Tests:	Specifications:	Results per batch:			
		2409104	2409105	2409102	2409103
pH	4.5 – 7.0	6.1	6.1	6.2	6.1
Iron	<1 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm
Heavy metals	<1 ppm	<0.04 ppm	<0.04 ppm	0.060 ppm	0.052 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	0.93 g/ 100ml	0.94 g/ 100ml	0.94 g/ 100ml	0.93 g/100ml

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:	
		2409192	2409190
Clarity	Transparent	Complies	Complies
Colour	Colourless	Complies	Complies
Extractable volume	≥ 10.00 mL	10.21 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

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

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09/12/2024

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