

QUALITY CERTIFICATE Certificate of Analysis (CoA)

Ref: 14364S - Syringe NaCl 0,9% Luer Lock 20 ml

Batch: 2409064

Expiry date: 2027-07

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

Tests:	Specifications:	Results per batch:		
		2406046	2406048	2406101
pH	4.5 – 7.0	6.2	6.2	6.5
Iron	<1 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm
Heavy metals	<1 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
NaCl Concentration	0.86-0.95 g/100mL	0.94 g/ 100ml	0.94 g/ 100ml	0.90 g/ 100ml

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:	
		2407059	2407080
Clarity	Transparent	Complies	Complies
Colour	Colourless	Complies	Complies
Extractable volume	≥ 20.00 mL	20.35 mL	20.30 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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04/11/2024

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