

QUALITY CERTIFICATE Certificate of Analysis (CoA)

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

Batch: 2411138

Expiry date: 2027-09

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

Tests:	Specifications:	Results per batch:		
		2409104	2409105	2409130
pH	4.5 – 7.0	6.1	6.1	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

Tests:	Specifications:	Results per batch:		
		2409151	2409150	2409152
pH	4.5 – 7.0	6.3	6.2	6.6
Iron	<1 ppm	0.0411 ppm	0.0403 ppm	<0.04 ppm
Heavy metals	<1 ppm	0.12 ppm	0.15 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	0.94 g/100ml	0.93 g/100ml	0.94 g/100ml

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:		
		2409192	2410044	2410093
Clarity	Transparent	Complies	Complies	Complies
Colour	Colourless	Complies	Complies	Complies
Extractable volume	≥ 10.00 mL	10.21 mL	10.04 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

Sterisets Manufacturing S.A.

Zona Industrial 1 – Lote 34 a 35, 4560-164 Guilhufe, Penafiel PORTUGAL

Phone: +31 412 236 606

www.sterisets.com

PART OF STI GROUP



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

23/12/2024