

QUALITY CERTIFICATE Certificate of Analysis (CoA)

Ref: 3040010- Syringe Water w/ Glycerine 10%, Luer, 10 ml - fill 10ml

Batch: 2412098

Expiry date: 2027-08

The following data are related to the Water w/ Glycerin 10% solution:

Tests:	Specifications:	Results per batch:			
		2411060	2407297	2407298	2409189
pH	4.5 – 7.0	7.0	6.8	6.5	6.4
Bacterial Endotoxins	< 4.5 EU/mL	<0.5 EU/mL	<0.5 EU/mL	4 EU/mL	<0.5 EU/mL
Glycerin Concentration	9.50-10.50 g/100mL	10.11 g/ 100ml	10.00 g/ 100ml	10.50 g/ 100ml	9.93 g/ 100ml

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:			
		2411132	2408057	2408056	2409212
Clarity	Transparent	Complies	Complies	Complies	Complies
Colour	Colourless	Complies	Complies	Complies	Complies
Extractable volume	≥ 10.00 mL	10.22 mL	10.09 mL	10.11 mL	10.00 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 water with Glycerine 10%, 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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04/02/2025

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