

QUALITY CERTIFICATE Certificate of Analysis (CoA)

Ref: 3040008 (Former: 14318BS) - Syringe Water w/ Glycerine 10%, Luer, 10ml

Batch: 2410037

Expiry date: 2027-08

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

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

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:	
		2408056	2408057
Clarity	Transparent	Complies	Complies
Colour	Colourless	Complies	Complies
Extractable volume	≥ 10.00 mL	10.11 mL	10.09 mL

The following data are related to the prefilled syringes final release testing:

Tests:	Specifications:	Result
Bacterial Endotoxins	< 4.5 EU/mL	<0.5 EU/mL

The above mentioned product prefilled syringe Glycerin 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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10/12/2024

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