

QUALITY CERTIFICATE Certificate of Analysis (CoA)

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

Batch: 2411039

Expiry date: 2027-09

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

| Tests: | Specifications: | Results per batch: | | | | |
|----------------------|-------------------|--------------------|---------------|---------------|--------------|--------------|
| | | 2408027 | 2408130 | 2408131 | 2409049 | 2409018 |
| pH | 4.5 – 7.0 | 6.8 | 6.4 | 6.1 | 6.3 | 6.7 |
| Iron | <1 ppm | <0.04 ppm | <0.04 ppm | <0.04 ppm | 0.0422 ppm | <0.04 ppm |
| Heavy metals | <1 ppm | <0.04 ppm | <0.04 ppm | <0.04 ppm | 0.047 ppm | <0.04 ppm |
| Bacterial Endotoxins | < 0.5 EU/mL | <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 | 0.94 g/ 100ml | 0.91 g/ 100ml | 0.93 g/ 100ml | 0.94 g/100ml | 0.89 g/100ml |

| Tests: | Specifications: | Results per batch: | | | | |
|----------------------|-------------------|--------------------|---------------|---------------|--------------|--------------|
| | | 2409020 | 2409102 | 2409103 | 2409053 | 2409054 |
| pH | 4.5 – 7.0 | 6.3 | 6.2 | 6.1 | 6.3 | 7.0 |
| Iron | <1 ppm | <0.04 ppm | <0.04 ppm | <0.04 ppm | <0.04 ppm | <0.04 ppm |
| Heavy metals | <1 ppm | <0.04 ppm | 0.060 ppm | <0.04 ppm | 0.048 ppm | <0.04 ppm |
| Bacterial Endotoxins | < 0.5 EU/mL | <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 | 0.92 g/ 100ml | 0.94 g/ 100ml | 0.93 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: | | | |
|--------------------|-----------------|--------------------|----------|----------|----------|
| | | 2409067 | 2409144 | 2409190 | 2409146 |
| Clarity | Transparent | Complies | Complies | Complies | Complies |
| Colour | Colourless | Complies | Complies | Complies | Complies |
| Extractable volume | ≥ 10.00 mL | 10.08 mL | 10.08 mL | 10.19 mL | 10.13 mL |

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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

Joana Pinto

09/12/2024