

Fresenius Kabi France

6, rue de Rempart
F-27400 Louviers

Laboratory

Certificate

Product: VSL EAU 500 ml FKNO/SE/DK/FI

Article: B230523

Batch No.: 13NBP061

Fabrication date:

1X500ML BOTTLE

2019/02/06

| Parameter Expected result/Dimension Test result/Dimension | Lower tol. limit / Lower limit (%) | Upper tol. limit / Upper Limit (%) | Evaluation |
|---|------------------------------------|------------------------------------|----------------|
| APPEARANCE --- | | | conform |
| EXTRACTABLE VOLUME Milliliter 517,0 Milliliter | 500,0 | | conform |
| CONDUCTIVITY $\mu\text{S/cm}$ 0,900 $\mu\text{S/cm}$ | | 5,000 | conform |
| ACIDITY OR ALCALINITY --- | | | conform |
| OXYDISABLE SUBTANCES --- | | | conform |
| CHLORIDE --- | | | conform |
| NITRATES $\leq 0,2$ ppm --- | | | conform |
| SULPHATES --- | | | conform |
| AMMONIUM $\leq 0,2$ ppm --- | | | conform |
| CALCIUM / MAGNESIUM --- | | | conform |
| LOSS ON DRYING % 0,000 % | | 0,003 | conform |

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| Expected result/Dimension | | | |
| Test result/Dimension | | | |
| BACTERIAL ENDOTOXINES < 0,25 IU/ml | | | |
| --- | | | |
| <0.015 ui/ml | | | conform |
| LABELLING | | | |
| --- | | | |
| | | | conform |
| SHELF LIFE | | | |
| --- | | | |
| 2021 09 | | | conform |
| REF. PCP 003 | | | |
| --- | | | |
| version 15 | | | conform |
| STERILITY | | | |
| --- | | | |
| | | | conform |
| FINAL CONTROL | | | |
| --- | | | |
| | | | conform |
| BATCH FILE COMPLIES | | | |
| --- | | | |
| | | | conform |

Released

This certificate is a computer print and valid without signature

Date: 2019/05/21 Quality Control Manager: Marie-Alix Vallot