

**ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS**

S.C. BISTRI-VET SRL  
LIBERTATII STR. 13  
420155 BISTRITA (JUD. BISTRITA-NASAUD)  
ROMANIA

Hoogstraten, 03.12.2019

**ORIGINAL**

**Material**

L130500-001079-01 CALCIKEL 300 500ML

Pharmaceutical Form:

Sterile solution

Batch 4006534 / Manufacturing Date 10.2019    Expiry date 10.2024

Inspection lot 40000047747 from 10.2019

**CERTIFICATION STATEMENT:** I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Formula: Calcium gluconate 279.24 mg - Magnesium chloride 40 mg - Boric acid 77.05 mg - Excipients q.s. ad 1 ml

Aspect: clear, almost colourless solution

| Characteristic               | Unit  | Value    | Lower Limit | Upper Limit |
|------------------------------|-------|----------|-------------|-------------|
| Aspect                       |       | Complies |             |             |
| Aspect (colour)              |       | Complies |             |             |
| Average volume (500 ml)      | %     | 101,00   | 100,00      | 102,00      |
| Relative density             |       | 1,164    | 1,150       | 1,170       |
| pH                           |       | 3,23     | 3,00        | 4,00        |
| Id: Calcium                  |       | Complies |             |             |
| Id: Magnesium                |       | Complies |             |             |
| Id: Gluconate                |       | Complies |             |             |
| Id: Chloride                 |       | Complies |             |             |
| Id: Methyl p-hydroxybenzoate |       | Complies |             |             |
| Assay: Calcium               | %     | 97,48    | 95,00       | 105,00      |
| Assay: Magnesium chloride    | %     | 98,12    | 95,00       | 105,00      |
| Assay: Methyl p-hydroxybenz  | %     | 99,31    | 90,00       | 110,00      |
| Sterility                    |       | Complies |             |             |
| Bacterial endotoxins         | IU/ML | 3        |             | 47          |

**CERTIFICATE OF CONFORMITY / QUALITY**

Date: 03/12/2019

**CALCIKEL 300 500 ML – batch 4006534 – exp. 10.2024**

The undersigned, KELA N.V., confirms that the product CALCIKEL 300 500 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product CALCIKEL 300 500 ML has been manufactured according to the formula of CALCIKEL which has been registered in Romania.

KELA N.V.



**kela**  
focus on health  
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