

CERTIFICATE OF CONFORMITY / QUALITY

Date: 02/10/2019

CALCIKEL 300 500 ML – batch 4005787 – exp. 08-2024

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 that they are for 100% C.E.E. 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.

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 01.10.2019

ORIGINAL
Material

L130500-001079-01 CALCIKEL 300 500ML

Pharmaceutical Form:

Sterile solution

Batch 4005787 / Manufacturing Date 08.2019 Expiry date 08.2024

Inspection lot 40000045922 from 08.2019

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)	%	100,42	100,00	102,00
Relative density		1,162	1,150	1,170
pH		3,29	3,00	4,00
Id: Calcium		Complies		
Id: Magnesium		Complies		
Id: Gluconate		Complies		
Id: Chloride		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Assay: Calcium	%	96,75	95,00	105,00
Assay: Magnesium chloride	%	97,69	95,00	105,00
Assay: Methyl p-hydroxybenz	%	98,45	90,00	110,00
Sterility		Complies		
Bacterial endotoxins	IU/ML	3		47