

CERTIFICATE OF CONFORMITY / QUALITY

Date: 06/12/2021

CALCIKEL 300 500 ML – batch 4012241 – exp. 09-2026

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
Sint Lenaartseweg 48
2320 Hoogstraten
Belgium

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 07.12.2021

ORIGINAL
Material

L130501-001079-01 CALCIKEL 300 500ML

Pharmaceutical Form:

Sterile solution

Batch 4012241 / Manufacturing Date 09.2021 Expiry date 09.2026

Inspection lot 40000062793 from 11.2021

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 (Y5-Y7)

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Aspect (colour)		Complies		
Average volume (500 ml)	%	101	100	102
Relative density		1,164	1,150	1,170
pH		3,2	3,0	4,0
Id: Calcium		Complies		
Id: Magnesium		Complies		
Id: Gluconate		Complies		
Id: Chloride		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Assay: Calcium	%	97,6	95,0	105,0
Assay: Magnesium chloride	%	96,7	95,0	105,0
Assay: Methyl p-hydroxybenz	%	94,7	90,0	110,0
Sterility		Complies		
Bacterial endotoxins	IU/ML	< 3		47