

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 30.09.2020

ORIGINAL

Material

L130501-001079-01 CALCIKEL 300 500ML

Pharmaceutical Form:

Sterile solution

Batch 4009240 / Manufacturing Date 08.2020 Expiry date 08.2025

Inspection lot 40000053901 from 08.2020

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)	%	100,00	100,00	102,00
Relative density		1,163	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	%	97,00	95,00	105,00
Assay: Magnesium chloride	%	98,40	95,00	105,00
Assay: Methyl p-hydroxybenz	%	96,90	90,00	110,00
Sterility		Complies		
Bacterial endotoxins	IU/ML	< 3		47

 **kela**
focus on health
Sint Lenaartseweg 48
2320 Hoogstraten
Belgium

Dig. Sign.: Van Buggenhout Kris
17.09.2020 14:10:34

Qualified Person

Conclusion:
Quality test complied

CERTIFICATE OF CONFORMITY / QUALITY

ORIGINAL

Date: 30/09/2020

CALCIKEL 300 500 ML – batch 4009240 – exp. 08.2025

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.

