

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 09.12.2020

ORIGINAL

Material

L130501-001079-01 CALCIKEL 300 500ML

Pharmaceutical Form:

Sterile solution

Batch 4010005 / Manufacturing Date 11.2020 Expiry date 11.2025

Inspection lot 40000056160 from 11.2020

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)	%	101,00	100,00	102,00
Relative density		1,164	1,150	1,170
pH		3,28	3,00	4,00
Id: Calcium		Complies		
Id: Magnesium		Complies		
Id: Gluconate		Complies		
Id: Chloride		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Assay: Calcium	%	95,54	95,00	105,00
Assay: Magnesium chloride	%	99,08	95,00	105,00
Assay: Methyl p-hydroxybenz	%	96,77	90,00	110,00
Sterility		Complies		
Bacterial endotoxins	IU/ML	< 3		47

CERTIFICATE OF CONFORMITY / QUALITY

Date: 08/12/2020

CALCIKEL 300 500 ML – batch 4010005 – exp. 11-2025

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.



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