

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 29.11.2023

ORIGINAL

Material

L130501-001079-01 CALCIKEL 300 500 ML

Pharmaceutical Form:

Sterile solution

Batch 4017360 / Manufacturing Date 09.2023 Expiry date 09.2028

Inspection lot 40000074573 from 11.2023

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)

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Aspect (colour)		Complies		
Average volume (500 ml)	%	101	100	102
Relative density		1,163	1,150	1,170
pH		3,3	3,0	4,0
Id: Calcium		Complies		
Id: Magnesium		Complies		
Id: Gluconate		Complies		
Id: Chloride		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Assay: Calcium	%	98,6	95,0	105,0
Assay: Magnesium chloride	%	101,8	95,0	105,0
Assay: Methyl p-hydroxybenz	%	99,2	90,0	110,0
Sterility		Complies		
Bacterial endotoxins	IU/ML	3		47