

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

NEWCO PHARM HUNGARIA KFT
RÁKÓCZI U. 142 - 146.
7100 SZEKSZÁRD
HUNGARY

Hoogstraten, 12.12.2018

ORIGINAL

Material

L130500-006994-01 NEOCAL-300 500 ML

Pharmaceutical Form:

Sterile solution

Batch 4003067 / Manufacturing Date 10.2018 Expiry date 10.2023

Inspection lot 40000038410 from 10.2018

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		
Average volume (500 ml)	%	100,00	100,00	102,00
Aspect (colour)		Complies		
Relative density		1,163	1,150	1,170
pH		3,25	3,00	3,60
Id: Calcium		Complies		
Id: Magnesium		Complies		
Id: Gluconate		Complies		
Id: Chloride		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Assay: Calcium	%	96,74	95,00	105,00
Assay: Magnesium chloride	%	101,29	95,00	105,00
Assay: Methyl p-hydroxybenz	%	99,13	90,00	105,00
Sterility		Complies		

 KELA N.V.
SINT LENAARTSEWEG 48
2320 HOOGSTRATEN
BELGIUM

Dig. Sign.: Van Buggenhout Kris
20.11.2018 16:08:11

Qualified Person

Conclusion:
Quality test complied