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SOP 426  
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ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 22.11.2017

Material

L130500-006994-01 NEOCAL 300 500 ML

Pharmaceutical Form:

Sterile solution

Batch 27774A10 / Manufacturing Date 10.2017 Expiry date 10.2022

Inspection lot 40000029020 from 09.2017

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		1,164	1,150	1,170
pH		3,30	3,00	3,60
Id: Calcium		Complies		
Id: Magnesium		Complies		
Id: Gluconate		Complies		
Id: Chloride		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Assay: Calcium	%	95,13	95,00	105,00
Assay: Magnesium chloride	%	97,34	95,00	105,00
Assay: Methyl p-hydroxybenz	%	95,91	90,00	105,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris  
31.10.2017 08:44:38

Qualified Person

Conclusion:  
Quality test complied