



KELA N.V.
St-Lenaartseweg 48
B-2320 Hoogstraten
Belgium

T. +32 3 340 04 11
F. +32 3 340 04 23
E-mail: info@kela.be
BTW BE 0403.835.645
RPR Turnhout

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, 30.08.2017

Material

D112016-006994-01 NEOVIT AD3E 100 ML

Pharmaceutical Form:

Sterile solution

Batch 26652B14 / Manufacturing Date 12.2016 Expiry date 12.2018

Inspection lot 40000023580 from 04.2017

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: Vitamin A 100.000 i.u. - vitamin D3 50.000 i.u. - Vitamin E 5 mg excipients q.s. ad 1 ml

Aspect: slightly opalescent yellow solution

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	101,30	98,00	102,00
pH		6,93	6,00	7,50
Relative density		1,020	1,010	1,025
Id: Vitamin A propionate		Complies		
Id: Vitamin D3		Complies		
Id: Vitamin E acetate		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Id: Propyl p-hydroxybenzoate		Complies		
Assay: Vitamin A propionate	%	112,27	95,00	115,00
Assay: Vitamin D3	%	96,73	95,00	105,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris
27.07.2017 08:01:42

Qualified Person

Conclusion:
Quality test complied