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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, 01.08.2016

Material

D112016-006994-01 NEOVIT AD3E 100 ML

Pharmaceutical Form:

Sterile solution

Batch 25714A11 / Manufacturing Date 06.2016 Expiry date 06.2018

Inspection lot 40000011151 from 05.2016

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)	%	101,00	98,00	102,00
pH		7,16	6,00	7,50
Relative density		1,021	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	%	104,15	95,00	115,00
Assay: Vitamin D3	%	100,88	95,00	105,00
Assay: Methyl p-hydroxybenz	%	96,92	90,00	105,00
Assay: Propyl p-hydroxybenz	%	98,46	90,00	105,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris  
12.07.2016 10:04:16

Qualified Person

Conclusion:  
Quality test complied