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SOP 426
Page 1/ 1

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 09.10.2017

Material

F802005-006994-01 ADEVIT 50/25/20 5 L

Pharmaceutical Form:

Non sterile solution

Batch 27733A10 / Manufacturing Date 09.2017 Expiry date 09.2019

Inspection lot 40000028007 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: Vitamin A 50000IU

Vitamin D3 25000IU

Vitamin E 20 mg

excipients q.s. ad 1 ml

Aspect: opalescent yellow liquid

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (5 l)	%	99,95	98,00	102,00
pH		5,79	5,00	7,50
Relative density		1,009	1,000	1,040
Id: Vitamin A propionate		Complies		
Id: Vitamin D3		Complies		
Id: Vitamin E acetate		Complies		
Assay: Vitamin A propionate	%	94,40	90,00	110,00
Assay: Vitamin D3	%	97,29	90,00	110,00
Assay: Vitamin E acetate	%	104,23	90,00	110,00

Dig. Sign.: Van Buggenhout Kris
05.10.2017 15:43:02

Qualified Person

Conclusion:
Quality test complied