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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, 04.10.2017

**Material**

**K404005-006994-01 SELEVIKEL ORAL SOL. 5 L**

Pharmaceutical Form:

Non sterile solution

Batch 27736A10 / Manufacturing Date 08.2017 Expiry date 08.2019

Inspection lot 40000027425 from 08.2017

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 E acetate 17 g - Sodium selenite equivalent with 50mg - excipients q.s. ad 1 L

Aspect: opalescent, pale yellow liquid

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (5 l)	%	99,89	98,00	102,00
Relative density		1,007	1,000	1,050
pH		5,94	4,50	6,50
Id: Vitamin E acetate		Complies		
Assay: Vitamin E acetate	%	100,34	90,00	130,00

Dig. Sign.: Van Buggenhout Kris  
26.09.2017 09:16:12

Qualified Person

Conclusion:  
Quality test complied