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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, 01.06.2018

ORIGINAL

Material

K404006-006994-01 SELEVIKEL ORAL SOL. 5 L

Pharmaceutical Form:

Non sterile solution

Batch 4001421 / Manufacturing Date 04.2018 Expiry date 04.2020

Inspection lot 40000033851 from 04.2018

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)	%	100,05	98,00	102,00
Relative density		1,008	1,000	1,050
pH		6,09	4,50	6,50
Id: Vitamin E acetate		Complies		
Assay: Vitamin E acetate	%	98,34	90,00	130,00

 KELA N.V.
SINT LENAARTSEWEG 48
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BELGIUM

Dig. Sign.: Van Buggenhout Kris
22.05.2018 14:35:46

Qualified Person

Conclusion:
Quality test complied