



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, 26.07.2017

Material

L107995-006994-01 AMINOVITA-KEL 5 L

Pharmaceutical Form:

Non sterile emulsion

Batch 27372A12 / Manufacturing Date 06.2017 Expiry date 06.2019

Inspection lot 40000024648 from 06.2017

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.

Aspect: clear orange to (dark) red liquid

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (5 l)	%	100,00	98,00	102,00
Relative density		1,015	1,010	1,020
pH		4,31	4,00	5,00
Id: Vitamin A propionate		Complies		
Id: Vitamin E acetate		Complies		
Assay: Vitamin A propionate	%	106,16	90,00	150,00
Assay: Vitamin E acetate	%	91,96	90,00	110,00

Dig. Sign.: Van Buggenhout Kris
11.07.2017 11:32:55

Qualified Person

Conclusion:
Quality test complied