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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, 08.11.2016

Material

L107995-006994-01 AMINOVITA-KEL 5 L

Pharmaceutical Form:

Non sterile emulsion

Batch 25884A11 / Manufacturing Date 06.2016 Expiry date 06.2018

Inspection lot 40000016943 from 10.2016

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.

Aspect: clear orange to (dark) red liquid

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (5 l)	%	100,20	98,00	102,00
Relative density		1,016	1,010	1,020
pH		4,30	4,00	5,00
Id: Vitamin A propionate		Complies		
Id: Vitamin E acetate		Complies		
Assay: Vitamin A propionate	%	107,66	90,00	150,00
Assay: Vitamin E acetate	%	99,13	90,00	110,00

Dig. Sign.: Janssens Michiel
02.11.2016 17:07:18

Qualified Person

Conclusion:
Quality test complied