



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

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ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 04.10.2017

Material

F713005-006994-01 NEOVIT FORTE 5 L

Pharmaceutical Form:

Non sterile emulsion

Batch 27735A10 / Manufacturing Date 09.2017

Expiry date 09.2019

Inspection lot 40000027656 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 A 50.000 IU - Vitamin D3 25.000 IU - Vitamin B1 10 mg - Vitamin B2 0,04 mg - Vitamin B6 1 mg - Vitamin B12 10 mcg - Vitamin E acetate 4 mg - D panthotenol 2 mg - nicotinamide 5 mg - mesoinositol 2 mg - methionine 5 mg - cholinecitrate 5 mg - Magnesiumsulphate 7 aqua 1 mg - Cobaltchloride 6 aqua 0,02 mg - coppersulfate 5 aqua 0,1 mg - Zinksulfate 1 aqua 0,062 mg - Mangesesulphate 1 aqua 0,1 mg - excipients q.s. ad 1 ml

Aspect: Clear yellow liquid with typical odour

Dig. Sign.: Van Buggenhout Kris
03.10.2017 16:34:19

Qualified Person

Conclusion:
Quality test complied



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Characteristics	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (5 l)	%	99,97	95,00	105,00
pH		3,89	3,50	4,50
Relative density		1,023	1,010	1,040
Id: Vitamin A propionate		Complies		
Id: Vitamin D3		Complies		
Id: Vitamin E acetate		Complies		
Id: Vitamin B1		Complies		
Id: Vitamin B3		Complies		
Id: Vitamin B6		Complies		
Id: Benzyl alcohol		Complies		
Assay: Vitamin A propionate	%	106,31	90,00	110,00
Assay: Vitamin D3	%	100,91	90,00	110,00
Assay: Vitamin E acetate	%	100,49	90,00	110,00
Assay: Vitamin B1	%	108,62	90,00	110,00
Assay: Vitamin B3	%	94,03	90,00	110,00
Assay: Vitamin B6	%	100,72	90,00	110,00
Assay: Benzyl alcohol	%	100,50	90,00	110,00

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