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RPR Turnhout

SOP 426
Page 1/ 2

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 26.07.2017

Material

D113X12-006994-01 NEOVIT FORTE 12 X 100 ML

Pharmaceutical Form:

Sterile solution

Batch 27184A16 / Manufacturing Date 06.2017 Expiry date 06.2019

Inspection lot 40000025144 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.

Formula: vit.A 50.000 I.U. - vit.D3 25.000 I.U. - vit.B1 10 mg - vit.B2 0,04 mg - vit.B6 1 mg - vit.B12 10 mcg - vit.E acetate 4 mg - pantothenol 2 mg - nicotinamide 5 mg - meso-inositol 2 mg - methionin 5 mg - choline citrate 5 mg - magnesium sulphate 7 aqua 1 mg - cobalt chloride 6 aqua 0,02 mg - copper sulfat 5 aqua 0,1 mg - zink sulphate 7

aqua 0,1 mg - manganese sulfat 1 aqua 0,1 mg - excipients q.s. ad 1 ml

Aspect: clear, yellow solution with typical odour

Dig. Sign.: Van Buggenhout Kris
18.07.2017 14:29:30

Qualified Person

Conclusion:
Quality test complied



Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	100,79	98,00	102,00
Relative density		1,025	1,010	1,040
pH		3,96	3,50	4,50
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: Dexpanthenol		Complies		
Id: Benzyl alcohol		Complies		
Assay: Vitamin A propionate	%	106,93	90,00	110,00
Assay: Vitamin D3	%	99,29	90,00	110,00
Assay: Vitamin E acetate	%	101,39	90,00	110,00
Assay: Vitamin B1	%	97,23	90,00	110,00
Assay: Vitamin B3	%	98,88	90,00	110,00
Assay: Vitamin B6	%	98,02	90,00	110,00
Assay: Dexpanthenol	%	98,15	90,00	110,00
Assay: Benzyl alcohol	%	101,53	90,00	110,00
Sterility		Complies		