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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, 12.12.2016

Material

L528005-006994-01 MULTIVIT CH 5 L

Pharmaceutical Form:

Non sterile solution

Batch 26569A10 / Manufacturing Date 11.2016 Expiry date 11.2018

Inspection lot 40000018005 from 11.2016

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.

Formula: Vitamin A 10000 I.U. - Vitamin D3 800 I.U. - Vitamin B1 0.8mg

- Vitamin B2 2 mg - Vitamin B6 1.6 mg - Vitamin E acetate 4 mg - Vit K3 600 mcg - Nicotinamide 2.4 mg - D-Panthenol 2.4 mg - DL-Methionine 2 mg

- Choline citrate 4 mg - Lysine HCl 4 mg - Manganese chelate eq. with 0.65 mg Mn - Iron chelate eq. with 0.135 mg Fe - Copperchelate eq with 0.035 mg Cu - Zinc chelate eq. with 0.45 mg Zn - Magnesium chelate eq. with 0.028 mg Mg - Cobalt sulphate eq. with 0.0067

mg Co - excipients q.s. ad 1 ml

Aspect: yellow solution

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (5 l)	%	100,17	98,00	102,00
pH		5,06	4,00	6,00
Relative density		1,035	1,010	1,040
Id: Vitamin A propionate		Complies		
Id: Vitamin E acetate		Complies		
Assay: Vitamin A propionate	%	91,30	90,00	110,00
Assay: Vitamin E acetate	%	99,96	90,00	110,00

Dig. Sign.: Van Buggenhout Kris
08.12.2016 11:06:31

Qualified Person

Conclusion:
Quality test complied