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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, 27.04.2016

Material

D095X12-006994-01 NEOVIT B COMPLEX 12 X 100 ML

Pharmaceutical Form:

Sterile solution

Batch 25393A16 / Manufacturing Date 03.2016 Expiry date 03.2018

Inspection lot 40000004730 from 03.2016

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 B1 10 mg - Vitamin B2 4 mg - Vitamin B6 4 mg - Nicotinamidum 25 mg - D Panthotenol 5 mg - Cyanocobalamine 10 µg - excipients q.s. ad 1 ml

Aspect: clear orange to slightly opalescent solution

Dig. Sign.: Van Buggenhout Kris
06.04.2016 15:51:34

Qualified Person

Conclusion:
Quality test complied



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Page 2/ 2

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	100,70	98,00	102,00
Relative density		1,015	1,005	1,035
pH		4,81	4,50	5,50
Id: Vitamin B1		Complies		
Id: Vitamin B2 phosphate		Complies		
Id: Vitamin B6		Complies		
Id: Vitamin B3		Complies		
Id: Dexpanthenol		Complies		
Id: Vitamin B12		Complies		
Id: Methyl p-hydroxybenzoate		Complies		
Assay: Vitamin B1	%	99,30	90,00	110,00
Assay: Vitamin B2 phosphate	%	97,90	90,00	110,00
Assay: Vitamin B6	%	99,90	90,00	110,00
Assay: Vitamin B3	%	99,30	90,00	110,00
Assay: Dexpanthenol	%	99,20	90,00	110,00
Assay: Vitamin B12	%	99,80	90,00	110,00
Assay: Methyl p-hydroxybenz	%	98,10	90,00	110,00
Sterility		Complies		