



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

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, 27.04.2016

Material

D112X12-006994-01 NEOVIT AD3E 12 X 100 ML

Pharmaceutical Form:

Sterile solution

Batch 23868.15 / Manufacturing Date 10.2015 Expiry date 10.2017

Inspection lot 40000008665 from 04.2016

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 100.000 i.u. - vitamin D3 50.000 i.u. - Vitamin E 5 mg excipients q.s. ad 1 ml

Aspect: slightly opalescent yellow solution

| Characteristic | Unit | Value | Lower Limit | Upper Limit |
|------------------------------|------|----------|-------------|-------------|
| Aspect | | Complies | | |
| Average volume (100 ml) | % | 101,40 | 98,00 | 102,00 |
| pH | | 7,17 | 6,00 | 7,50 |
| Relative density | | 1,019 | 1,010 | 1,025 |
| Id: Vitamin A propionate | | Complies | | |
| Id: Vitamin D3 | | Complies | | |
| Id: Vitamin E acetate | | Complies | | |
| Id: Methyl p-hydroxybenzoate | | Complies | | |
| Id: Propyl p-hydroxybenzoate | | Complies | | |
| Assay: Vitamin A propionate | % | 111,53 | 95,00 | 115,00 |
| Assay: Vitamin D3 | % | 99,48 | 95,00 | 105,00 |
| Assay: Methyl p-hydroxybenz | % | 95,56 | 90,00 | 105,00 |
| Assay: Propyl p-hydroxybenz | % | 95,53 | 90,00 | 105,00 |
| Sterility | | Complies | | |

Dig. Sign.: Van Buggenhout Kris
22.04.2016 16:37:41

Qualified Person

Conclusion:
Quality test complied