

# KELA LABORATORIA N.V.

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RPR Turnhout

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Established in 1941

## ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

Produkt - Produit - Product <i>DOG ECZEMA 100 GR</i>			NEWCO PHARM HUNGARIA KFT RAKOCZI U. 146 7100 SZEKSZARD  Z.Hd: Dr. Varga
Farm. Vorm - Pharm. Form <i>EMULSION</i>			
Art. No. F829100			
Batch Nr.	MAN:	EXP	
19807.18	06-2013	06-2015	Hoogstraten, 15.11.13

### Formula :

Prednisolone 1 mg  
Neomycinesulfate equivalent with 5000 IU Neomycine base  
Precipitated Sulphur 5 mg  
Zink Oxide 30 mg  
Excipients q.s. ad 1g

### Tests Performed

Appearance  
Theoretical weight  
Average weight  
pH  
Particle size  
Resuspendability

### Specifications

Yellowish white emulsion  
100 g / 500 g  
95 - 105 %  
5,0 - 7,5  
90 % < 150 micrometers  
homog. after 5 shakings

### Results

Yellowish white emulsion  
100 g / 500 g  
99,6 % / 100,4 %  
7,10  
complies  
complies

### Identifications

Prednisolone  
Neomycinesulphate  
Sulphur  
Zinc Oxyde  
Methylhydroxybenzoate

positive  
positive  
positive  
positive  
positive

positive  
positive  
positive  
positive  
positive

### Assays

Prednisolone  
Neomycinesulphate  
Sulphur  
Zinc Oxyde  
Methylhydroxybenzoate

95 - 105 %  
90 - 110 %  
95 - 105 %  
95 - 105 %  
90 - 110 %

100,02 %  
101,78 %  
102,01 %  
96,52 %  
98,42 %

### Conclusion

CONFORM

### BATCH RELEASE CERTIFICATE :

We declare that this batch has been manufactured and packed according to current GMP rules and has been released into the market.

**KELA LABORATORIA N.V.**  
N. VAN EEGHEM  
Kris Van Buggenhout  
Industrial Pharmacist  
Ind. Pharm. Cert. N. 1562