

CERTIFICATE OF CONFORMITY / QUALITY

Date: 02/10/2019

FLORFENIKEL 30% 100 ML – batch 4005531 – exp. 05/2022

The undersigned, KELA N.V., confirms that the product FLORFENIKEL 30% 100 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product FLORFENIKEL 30% 100 ML has been manufactured according to the formula of FLORFENIKEL which has been registered in Romania.

KELA N.V.



kela
focus on health

Sint Lenaartseweg 48
2320 Hoogstraten
Belgium

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

S.C. BISTRI-VET SRL
 LIBERTATII STR. 13
 420155 BISTRITA (JUD. BISTRITA-NASAUD)
 ROMANIA

Hoogstraten, 01.10.2019

ORIGINAL
Material

L470100-001079-01 FLORFENIKEL 30% 100 ML

Pharmaceutical Form:

Sterile solution

Batch 4005531 / Manufacturing Date 05.2019 Expiry date 05.2022

Inspection lot 40000043863 from 05.2019

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: Florfenicol 300mg - excipients q.s. ad 1 ml

Aspect: clear, light yellow to yellow solution (< Y3)

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Aspect (colour)		Complies		
Average volume (100 ml)	%	100,60	100,00	102,00
Viscosity	mPa.s	33	25	150
Relative density		1,235	1,180	1,280
Visible particles		Absent		
Id: Florfenicol		Complies		
Assay: Florfenicol	%	98,65	95,00	105,00
Sterility		Complies		