

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 03.12.2019

ORIGINAL

Material

L470250-001079-01 FLORFENIKEL 30% 250 ML

Pharmaceutical Form:

Sterile solution

Batch 4006280 / Manufacturing Date 10.2019 Expiry date 10.2022

Inspection lot 40000047390 from 10.2019

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 (250 ml)	%	100,78	100,00	102,00
Viscosity	mPa.s	35	25	150
Relative density		1,237	1,180	1,280
Visible particles		Absent		
Id: Florfenicol		Complies		
Assay: Florfenicol	%	99,54	95,00	105,00
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 03/12/2019

FLORFENIKEL 30% 250 ML – batch 4006280 – exp. 10.2022

The undersigned, KELA N.V., confirms that the product FLORFENIKEL 30% 250 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% 250 ML has been manufactured according to the formula of FLORFENIKEL 30% which has been registered in Romania.

KELA N.V.



Sint Lenaartseweg 48
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Belgium

