

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 16.11.2021

ORIGINAL**Material**

L470250-001079-01 FLORFENIKEL 30% 250 ML

Pharmaceutical Form:

Sterile solution

Batch 4012460 / Manufacturing Date 07.2021 Expiry date 07.2024

Inspection lot 40000061683 from 09.2021

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 - excipiens 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		
Extractable volume (250 ml) (N	%	100	100	
Viscosity	mPa.s	43	25	150
Relative density		1,237	1,180	1,280
Visible particles		Absent		
Id: Florfenicol		Complies		
Assay: Florfenicol	%	98,2	95,0	105,0
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 15/11/2021

FLORFENIKEL 30% 250 ML – batch 4012460 – exp. 07.2024

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.



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focus on health

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