

CERTIFICATE OF CONFORMITY / QUALITY

Date: 07/07/2021

FLORFENIKEL 30% 100 ML – batch 4011215 – exp. 06-2024

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 that they are for 100% C.E.E. origin.

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

KELA N.V.



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ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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LIBERTATII STR. 13
420155 BISTRITA (JUD. BISTRITA-NASAUD)
ROMANIA

Hoogstraten, 05.07.2021

ORIGINAL**Material**

L470100-001079-01 FLORFENIKEL 30% 100 ML

Pharmaceutical Form:

Sterile solution

Batch 4011215 / Manufacturing Date 06.2021 Expiry date 06.2024

Inspection lot 40000059821 from 06.2021

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 - 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		
Extractable volume (100 ml) (N	%	101	100	
Viscosity	mPa.s	35	25	150
Relative density		1,236	1,180	1,280
Visible particles		Absent		
Id: Florfenicol		Complies		
Assay: Florfenicol	%	98,5	95,0	105,0
Sterility		Complies		