

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 12.05.2020

ORIGINAL

Material
L470250-001079-01 FLORFENIKEL 30% 250 ML
Pharmaceutical Form:
Sterile solution
Batch 4007602 / Manufacturing Date 03.2020 Expiry date 03.2023

Inspection lot 40000050457 from 03.2020

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)	%	100,58	100,00	102,00
Viscosity	mPa.s	40	25	150
Relative density		1,238	1,180	1,280
Visible particles		Absent		
Id: Florfenicol		Complies		
Assay: Florfenicol	%	99,85	95,00	105,00
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 12/05/2020

FLORFENIKEL 30% 250 ML – batch 4007602 – exp. 03.2023

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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Belgium