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SOP 426
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ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 11.10.2018

ORIGINAL

Material

L470250-001079-01 FLORFENIKEL 30% 250 ML

Pharmaceutical Form:

Sterile solution

Batch 4002733 / Manufacturing Date 07.2018 Expiry date 07.2020

Inspection lot 40000037995 from 09.2018

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)	%	100,54	100,00	102,00
Viscosity	mPa.s	36	25	150
Relative density		1,236	1,180	1,280
Visible particles		Absent		
Id: Florfenicol		Complies		
Assay: Florfenicol	%	99,01	95,00	105,00
Sterility		Complies		



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Dig. Sign.: Van Buggenhout Kris
01.10.2018 13:50:28

Qualified Person

Conclusion:
Quality test complied