

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

ORIGINAL

Hoogstraten, 09.04.2021

Material

L076100-001079-01 CEFOKEL 50 MG/ML 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4010996 / Manufacturing Date 11.2020 Expiry date 11.2023

Inspection lot 40000058282 from 03.2021

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: Cefotiofur HCl equivalent with 50 mg Cefotiofur - excipients q.s. ad 1 ml

Aspect: white to off-white, beige suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	103	100	110
Relative density		0,894	0,860	0,960
Water content	%	0,2		0,2
Particle size: x90	µm	8		10
Resuspendability	s	< 20		20
Id: Cefotiofur HCL		Complies		
Assay: Cefotiofur	%	98,3	95,0	105,0
Rls: D3- anti oxime cefotiofur	%	< 0,3		1,0
Rls: any other imp	%	< 0,3		1,0
Rls: sum of imp	%	< 0,3		3,0
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 08/04/2021

CEFOKEL 50 MG/ML 100 ML – batch 4010996 – exp. 11-2023

The undersigned, KELA N.V., confirms that the product CEFOKEL 50 MG/ML 100 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product CEFOKEL 50 MG/ML 100 ML has been manufactured according to the formula of CEFOKEL 50 MG/ML which has been registered in Romania.

KELA N.V.



Sint Lenaartseweg 48
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Belgium