

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 21.09.2021

ORIGINAL**Material**

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

Pharmaceutical Form:

Sterile suspension

Batch 4011598 / Manufacturing Date 02.2021 Expiry date 02.2024

Inspection lot 40000060549 from 07.2021

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		
Extractable volume (100 ml)	%	104	100	110
Relative density		0,893	0,860	0,960
Water content	%	0,2		0,2
Particle size: x90	µm	7		10
Resuspendability	s	< 20		20
Id: Cefotiofur HCL		Complies		
Assay: Cefotiofur	%	99,6	95,0	105,0
Rls: D3- anti oxime cefotiofur	%	0,5		1,0
Rls: any other imp	%	< 0,3		1,0
Rls: sum of imp	%	0,5		3,0
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 21/09/2021

CEFOKEL 50 MG/ML 100 ML – batch 4011598 – exp. 02.2024

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.



 **kela**
focus on health
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