

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 16.03.2023

ORIGINAL

Material
L076100-001079-01 CEFOKEL 50 MG/ML 100 ML
Pharmaceutical Form:
Sterile suspension
Batch 4015391 / Manufacturing Date 11.2022 Expiry date 11.2025

Inspection lot 40000070085 from 01.2023

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: Ceftiofur HCl equivalent with 50 mg Ceftiofur - 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)	%	102	100	110
Relative density		0,894	0,860	0,960
Water content	%	0,1		0,2
Particle size: x90	µm	5		10
Resuspendability	s	17		20
Id: Ceftiofur HCL		Complies		
Assay: Ceftiofur	%	98,4	95,0	105,0
Rls: D3- anti oxime ceftiofur	%	< 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: 15/03/2023

CEFOKEL 50 MG/ML 100 ML – batch 4015391 – exp. 11.2025

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
Sint Lenaartseweg 48
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Belgium


Kris Van Leeghendam
QA Release Manager
QP 1562
KELA N.V. 15/03/23

Kela nv

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