

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 11.07.2022

ORIGINAL
Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4013585 / Manufacturing Date 08.2021 Expiry date 08.2024

Inspection lot 40000065940 from 04.2022

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	%	0,2		0,2
Particle size: x90	µm	6		10
Resuspendability	s	< 20		20
Id: Ceftiofur HCL		Complies		
Assay: Ceftiofur	%	101,3	95,0	105,0
Rls: D3- anti oxime ceftiofur	%	0,4		1,0
Rls: any other imp	%	< 0,3		1,0
Rls: sum of imp	%	0,4		3,0
Sterility		Complies		

 Dig. Sign.: Van Buggenhout Kris
 16.05.2022 16:03:37

Qualified Person

 Conclusion:
 Quality test complied

CERTIFICATE OF CONFORMITY / QUALITY

Date: 07/07/2022

CEFOKEL 50 MG/ML 100 ML – batch 4013585 – exp. 08.2024

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** Sint Lenaartseweg 48
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Belgium


Kris Van Buggenhout
QA Release Manager
QP 1562
KELA N.V.

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