

CERTIFICATE OF CONFORMITY / QUALITY

Date: 02/10/2019

CEFOKEL 50 MG/ML 100 ML – batch 4005737 – exp. 07/2021

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 that they are for 100% C.E.E. origin.

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

KELA N.V.

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 01.10.2019

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4005737 / Manufacturing Date 07.2018 Expiry date 07.2021

Inspection lot 40000044686 from 06.2019

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		
Average volume (100 ml)	%	100,48	100,00	110,00
Relative density		0,894	0,860	0,960
Water content	%	0,11		0,20
Particle size: x90	µm	4,7		10,0
Resuspendability	s	< 20		20
Id: Ceftiofur HCL		Complies		
Assay: Ceftiofur	%	99,25	95,00	105,00
Rls: D3- anti oxime ceftiofur	%	0,24		1,00
Rls: any other imp	%	< 0,30		1,00
Rls: sum of imp	%	< 0,30		3,00
Sterility		Complies		