

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

ORIGINAL

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

Hoogstraten, 05.03.2019

Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4004145 / Manufacturing Date 01.2018 Expiry date 01.2021

Inspection lot 40000040741 from 01.2019

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)	%	101,30	100,00	110,00
Relative density		0,893	0,860	0,960
Water content	%	0,11		0,20
Particle size: x90	µm	5,8		10,0
Resuspendability	s	< 20		20
Id: Ceftiofur HCL		Complies		
Assay: Ceftiofur	%	96,87	95,00	105,00
Rls: D3- anti oxime ceftiofur	%	< 0,30		1,00
Rls: any other imp	%	0,16		1,00
Rls: sum of imp	%	< 0,30		3,00
Sterility		Complies		