

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 13.01.2023

ORIGINAL
Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4015185 / Manufacturing Date 10.2022 Expiry date 10.2025

Inspection lot 40000069620 from 12.2022

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		0,895	0,860	0,960
Water content	%	0,1		0,2
Particle size: x90	µm	4		10
Resuspendability	s	< 20		20
Id: Ceftiofur HCL		Complies		
Assay: Ceftiofur	%	101,0	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		