

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 28.11.2024

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4019954 / Manufacturing Date 08.2024 Expiry date 08.2027

Inspection lot 40000079439 from 10.2024

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: Cefotiofur HCl equivalent with 50 mg Cefotiofur - 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)	%	101	100	110
Relative density		0,895	0,860	0,960
Water content	%	0,2		0,2
Particle size: x90	µm	5		10
Resuspendability	s	4		20
Id: Cefotiofur HCL		Complies		
Assay: Cefotiofur	%	97,5	95,0	105,0
Rls: D3- anti oxime cefotiofur	%	0,3		1,0
Rls: any other imp	%	0,2		1,0
Rls: sum of imp	%	0,0		3,0
Sterility		Complies		