

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 27.11.2024

ORIGINAL

Material

F687180-001079-01 DRYCLOXAKEL 20 X 9GR

Pharmaceutical Form:

Sterile intramammary ointment

Batch 4019554 / Manufacturing Date 10.2024 Expiry date 10.2027

Inspection lot 40000079129 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: Cloxacilline benzathine 1000 mg - excipients q.s. ad 9 g

Aspect: white to pale yellow, oily suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Deliverable mass (9 g)	%	101	90	110
Particle size: x50	µm	3		15
Particle size: x90	µm	9		30
Viscosity (NLT)	mPa.s	720	350	
Id: Cloxacilline		Complies		
Id: Benzathine		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Cloxacilline benzathine	%	92,6	92,0	108,0
Assay: Butylhydroxytoluene	%	96,6	90,0	110,0
Sterility		Complies		