

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 21.09.2021

ORIGINAL**Material**

F687180-001079-01 DRYCLOXAKEL 20 X 9GR

Pharmaceutical Form:

Sterile intramammary ointment

Batch 4011937 / Manufacturing Date 08.2021 Expiry date 08.2024

Inspection lot 40000060802 from 07.2021

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: a 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	4		15
Particle size: x90	µm	10		30
Viscosity (NLT)	mPa.s	446	350	
Id: Cloxacilline		Complies		
Id: Benzathine		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Cloxacilline benzathine	%	102,0	92,0	108,0
Assay: Butylhydroxytoluene	%	96,9	90,0	110,0
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 21/09/2021

DRYCLOXAKEL 20 x 9 GR – batch 4011937 – exp. 08.2024

The undersigned, KELA N.V., confirms that the product DRYCLOXAKEL 20 x 9 GR has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product DRYCLOXAKEL 20 x 9 GR has been manufactured according to the formula of DRYCLOXAKEL which has been registered in Romania.

KELA N.V.



Sint Lenaartseweg 48
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Belgium