

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 08.10.2020

ORIGINAL

Material

F687180-001079-01 DRYCLOXAKEL 20 X 9GR

Pharmaceutical Form:

Sterile intramammary ointment

Batch 4009304 / Manufacturing Date 07.2020 Expiry date 07.2023

Inspection lot 40000053152 from 07.2020

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)	%	100,97	90,00	110,00
Particle size: x50	µm	3,7		15,0
Particle size: x90	µm	11,3		30,0
Viscosity (NLT)	mPa.s	906	350	
Id: Cloxacilline		Complies		
Id: Benzathine		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Cloxacilline benzathine	%	100,60	92,00	108,00
Assay: Butylhydroxytoluene	%	95,78	90,00	110,00
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 06/10/2020

DRYCLOXAKEL 20 x 9GR – batch 4009304 – exp. 07.2023

The undersigned, KELA N.V., confirms that the product DRYCLOXAKEL 20 x 9GR 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 9GR has been manufactured according to the formula of DRYCLOXAKEL which has been registered in Romania.

KELA N.V.



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