

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 11.06.2019

ORIGINAL
Material

F687180-001079-01 DRYCLOXAKEL 20 X 9GR

Pharmaceutical Form:

Sterile intramammary ointment

Batch 4002863 / Manufacturing Date 09.2018 Expiry date 09.2021

Inspection lot 40000037698 from 09.2018

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)	%	101,41	90,00	110,00
Particle size: x50	µm	5,9		15,0
Particle size: x90	µm	21,6		30,0
Viscosity (NLT)	mPa.s	1370	350	
Id: Cloxacilline		Complies		
Id: Benzathine		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Cloxacilline benzathine	%	107,05	95,00	105,00
Assay: Butylhydroxytoluene	%	95,54	90,00	110,00
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 14/06/2019

Conc.: DRYCLOXAKEL (20 X 9G) – batch 4002863– exp. 09-2021

The undersigned, KELA N.V., confirms that the product DRYCLOXAKEL (20 X 9G) has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and that they are for 100% C.E.E. origin.

The product DRYCLOXAKEL (20 X 9G) has been manufactured according to the formula of DRYCLOXAKEL which has been registered in Romania.

KELA N.V.