

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 13.08.2019

ORIGINAL

Material
 K847997-001079-01 TYLOSIN 75% KELA 1 KG
 Pharmaceutical Form:
 Non sterile powder
 Batch 4005731 / Manufacturing Date 07.2019 Expiry date 07.2022

Inspection lot 40000045330 from 07.2019

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: tylosine tartrate eq 750 mg tylosine - excipients q.s. ad 1 g

Aspect: white to light yellow powder, free of conglomerates

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average mass (1000 g)	%	100,41	95,00	105,00
Water content	%	3,74		4,50
pH of solution		6,33	5,00	7,20
Id (A) (UV - 290 nm): Tylosin		Complies		
Id (B) (UV - 332 nm): Tylosin		Complies		
Id: Tartrate		Complies		
Assay (Micro): Tylosin	%	104,0	90,0	110,0

CERTIFICATE OF CONFORMITY / QUALITY

Date: 13/08/2019

TYLOSIN 75% KELA 1 KG – batch 4005731 – exp. 07/2022

The undersigned, KELA N.V., confirms that the product TYLOSIN 75% KELA 1 KG has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product TYLOSIN 75% KELA 1 KG has been manufactured according to the formula of TYLOSIN 75% KELA which has been registered in Romania.

KELA N.V.



kela
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