

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 05.03.2025

ORIGINAL

Material

K847997-001079-01 TYLOSIN 75% KELA 1 KG

Pharmaceutical Form:

Non sterile powder (HCP)

Batch 4019682 / Manufacturing Date 10.2024 Expiry date 10.2027

Inspection lot 40000080431 from 01.2025

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 buff-coloured powder free from conglomerates

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average mass (1000 g)	%	101	95	105
Water content	%	2,5		4,5
pH of solution		6,0	5,0	7,2
Id (A) (UV - 290 nm): Tylosin		Complies		
Id (B) (UV - 332 nm): Tylosin		Complies		
Id: Tartrate		Complies		
Assay (Micro): Tylosin	%	109,5	90,0	110,0