

**ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS**

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

Hoogstraten, 06.05.2022

**ORIGINAL**
**Material**

K847997-001079-01 TYLOSIN 75% KELA 1 KG

Pharmaceutical Form:

Non sterile powder (HCP)

Batch 4013443 / Manufacturing Date 03.2022 Expiry date 03.2025

Inspection lot 40000065172 from 03.2022

**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)         | %    | 100      | 95          | 105         |
| Water content                 | %    | 1,7      |             | 4,5         |
| pH of solution                |      | 6,3      | 5,0         | 7,2         |
| Id (A) (UV - 290 nm): Tylosin |      | Complies |             |             |
| Id (B) (UV - 332 nm): Tylosin |      | Complies |             |             |
| Id: Tartrate                  |      | Complies |             |             |
| Assay (Micro): Tylosin        | %    | 95,0     | 90,0        | 110,0       |