

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

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

**ORIGINAL**

Hoogstraten, 13.08.2019

**Material**

L470250-001079-01 FLORFENIKEL 30% 250 ML

**Pharmaceutical Form:**

Sterile solution

Batch 4005535 / Manufacturing Date 05.2019    Expiry date 05.2022

Inspection lot 40000044550 from 06.2019

**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: Florfenicol 300mg - excipients q.s. ad 1 ml

Aspect: clear, light yellow to yellow solution (&lt; Y3)

| Characteristic          | Unit  | Value    | Lower Limit | Upper Limit |
|-------------------------|-------|----------|-------------|-------------|
| Aspect                  |       | Complies |             |             |
| Aspect (colour)         |       | Complies |             |             |
| Average volume (250 ml) | %     | 100,55   | 100,00      | 102,00      |
| Viscosity               | mPa.s | 33       | 25          | 150         |
| Relative density        |       | 1,235    | 1,180       | 1,280       |
| Visible particles       |       | Absent   |             |             |
| Id: Florfenicol         |       | Complies |             |             |
| Assay: Florfenicol      | %     | 96,60    | 95,00       | 105,00      |
| Sterility               |       | Complies |             |             |

## CERTIFICATE OF CONFORMITY / QUALITY

Date: 13/08/2019

### **FLORFENIKEL 30% 250 ML – batch 4005535 – exp. 05/2022**

The undersigned, KELA N.V., confirms that the product FLORFENIKEL 30% 250 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product FLORFENIKEL 30% 250 ML has been manufactured according to the formula of FLORFENIKEL 30% which has been registered in Romania.

KELA N.V.



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Kela nv

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