

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

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

Hoogstraten, 19.08.2020

**ORIGINAL****Material**

F699995-001079-01 TRIMAZIN 30% 1 KG

**Pharmaceutical Form:**

Non sterile powder (HCP)

Batch 4008617 / Manufacturing Date 11.2019 Expiry date 11.2022

Inspection lot 40000053260 from 07.2020

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: Sulfadiazine sodium eq. with 250 mg sulfadiazine -  
Trimethoprim  
50 mg - excipients q.s.ad 1 g

Aspect: white to off-white powder

| Characteristic          | Unit | Value    | Lower Limit | Upper Limit |
|-------------------------|------|----------|-------------|-------------|
| Aspect                  |      | Complies |             |             |
| Water content           | %    | 3        |             | 5           |
| Id: Sodium sulfadiazine |      | Complies |             |             |
| Id: Trimethoprim        |      | Complies |             |             |
| Assay: Sulfadiazine     | %    | 100,8    | 95,0        | 105,0       |
| Assay: Trimethoprim     | %    | 101,3    | 95,0        | 105,0       |

**CERTIFICATE OF CONFORMITY / QUALITY**

Date: 19/08/2020

**TRIMAZIN 30% 1 KG – batch 4008617– exp. 11-2022**

The undersigned, KELA N.V., confirms that the product TRIMAZIN 30% 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 TRIMAZIN 30% 1 KG has been manufactured according to the formula of TRIMAZIN 30% which has been registered in Romania.

KELA N.V.



 **kela**  
focus on health  
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