

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 04.02.2020

ORIGINAL**Material**

F699995-001079-01 TRIMAZIN 30% 1 KG

Pharmaceutical Form:

Non sterile powder

Batch 4007098 / Manufacturing Date 11.2019 Expiry date 11.2022

Inspection lot 40000048392 from 11.2019

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: 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		
Average mass	%	100,38	95,00	105,00
Water content	%	3,39		5,00
Id: Sodium sulfadiazine		Complies		
Id: Trimethoprim		Complies		
Assay: Sulfadiazine	%	100,83	95,00	105,00
Assay: Trimethoprim	%	101,26	95,00	105,00

ORIGINAL

CERTIFICATE OF CONFORMITY / QUALITY

Date: 04/02/2020

TRIMAZIN 30% 1 KG – batch 4007098– 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
Sint Lenaartseweg 48
2320 Hoogstraten
Belgium