

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 12.06.2019

ORIGINAL**Material**

F699995-001079-01 TRIMAZIN 30% 1 KG

Pharmaceutical Form:

Non sterile powder

Batch 4005228 / Manufacturing Date 04.2017 Expiry date 04.2020

Inspection lot 40000044020 from 05.2019

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 equivalent with 250 mg sulfadiazine

Trimethoprim 50 mg

excipients q.s.ad 1 g

Aspect: white to off-white powder, free of conglomerates

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average mass	%	99,94	95,00	105,00
Water content	%	3,64		5,00
Id: Sodium sulfadiazine		Complies		
Id: Trimethoprim		Complies		
Assay: Sulfadiazine	%	100,58	95,00	105,00
Assay: Trimethoprim	%	97,01	95,00	105,00

CERTIFICATE OF CONFORMITY / QUALITY

Date: 14/06/2019

Conc.: TRIMAZIN 30% (1 KG) – batch 4005228 - exp. 04-2020

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 that they are for 100% C.E.E. 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 nv

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