

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 12.07.2022

ORIGINAL

Material

F699995-001079-01 TRIMAZIN 30% 1 KG

Pharmaceutical Form:

Non sterile powder (HCP)

Batch 4013579 / Manufacturing Date 05.2022 Expiry date 05.2025

Inspection lot 40000066329 from 05.2022

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

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

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average mass (1 kg)	%	101	95	105
Water content	%	3,0		5,0
Id: Sodium sulfadiazine		Complies		
Id: Trimethoprim		Complies		
Assay: Sulfadiazine	%	98,8	95,0	105,0
Assay: Trimethoprim	%	99,9	95,0	105,0

CERTIFICATE OF CONFORMITY / QUALITY

Date: 07/07/2022

TRIMAZIN 30% 1 KG – batch 4013579– exp. 05.2025

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.

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QA Release Manager
QP 1562
KELA N.V.

Kela nv

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