

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 29.04.2019

ORIGINAL

Material

S888992-001079-01 AMOXYCILIN 70% 1 KG

Pharmaceutical Form:

Non sterile powder

Batch 4004973 / Manufacturing Date 04.2019 Expiry date 04.2022

Inspection lot 40000042775 from 03.2019

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: Amoxycillinetrihydrate equivalent with 700 mg Amoxycilline - excipients q.s. ad 1 g

Aspect: white to almost white powder free from conglomerates

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average mass (1 kg)	%	100,80	95,00	105,00
pH of solution		7,94	7,00	8,00
Water content (between)	%	13,03	11,00	15,50
Id: Amoxicillin		Complies		
Assay: Amoxicillin	%	99,51	95,00	105,00

CERTIFICATE OF CONFORMITY / QUALITY

Date: 02/05/2019

Conc.: AMOXYCILIN 70% (1 KG) – batch 4004973– exp. 04-2022

The undersigned, KELA N.V. confirms that the product AMOXYCILIN 70% (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 Amoxycilin 70% (1kg) has been manufactured according to the formula of Amoxycilin 70% which has been registered in Romania.

KELA N.V.



kela
focus on health
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