

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 08.04.2020

ORIGINAL

Material

C614100-001079-01 AMOXY-KEL 15% 100 ML

Pharmaceutical Form:

Sterile suspension

Batch 4007092 / Manufacturing Date 02.2020 Expiry date 02.2023

Inspection lot 40000049639 from 01.2020

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: Amoxicillin trihydrate eq.150 mg amoxicillin base excipients q.s.ad 1 ml

Aspect: white to pale yellow suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml)	%	100,12	98,00	102,00
Resuspendability	ROT	14		20
Relative density		0,983	0,950	1,000
Viscosity	mPa.s	71	20	200
Needling time	s	20		30
Id: Amoxicillin trihydrate		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Amoxicillin	%	97,61	95,00	105,00
Assay: Butylhydroxytoluene	%	100,17	90,00	110,00
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 07/04/2020

AMOXY-KEL 15% 100 ML – batch 4007092 – exp. 02.2023

The undersigned, KELA N.V., confirms that the product AMOXY-KEL 15% 100 ML has been manufactured according to the methods of "Good Manufacturing Practices" at our factory in Hoogstraten and is of EU origin.

The product AMOXY-KEL 15% 100 ML has been manufactured according to the formula of AMOXY-KEL 15% which has been registered in Romania.

KELA N.V.



kela
focus on health
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