

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 03.12.2019

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4006569 / Manufacturing Date 09.2019 Expiry date 09.2022

Inspection lot 40000048457 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: 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)	%	100,80	98,00	102,00
Resuspendability	ROT	20		20
Relative density		0,980	0,950	1,000
Viscosity	mPa.s	56	20	200
Needling time	s	16		30
Id: Amoxicillin trihydrate		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Amoxicillin	%	97,62	95,00	105,00
Assay: Butylhydroxytoluene	%	99,19	90,00	110,00
Sterility		Complies		

CERTIFICATE OF CONFORMITY / QUALITY

Date: 03/12/2019

AMOXY-KEL 15% 100 ML – batch 4006569 – exp. 09.2022

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.



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