

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

ORIGINAL

Hoogstraten, 08.07.2021

Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4011294 / Manufacturing Date 06.2021 Expiry date 06.2024

Inspection lot 40000059688 from 06.2021

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)	%	100,73	98,00	102,00
Resuspendability	ROT	8		20
Relative density		0,983	0,950	1,000
Viscosity	mPa.s	51	20	200
Needling time	s	20		30
Id: Amoxicillin trihydrate		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Amoxicillin	%	98,10	95,00	105,00
Assay: Butylhydroxytoluene	%	99,00	90,00	110,00
Sterility		Complies		

Dig. Sign.: Van Buggenhout Kris
07.07.2021 10:11:16

Qualified Person

Conclusion:
Quality test complied

CERTIFICATE OF CONFORMITY / QUALITY

Date: 07/07/2021

Conc.: AMOXY-KEL 15% (100ML) – batch 4011294– exp. 06-2024

The undersigned, KELA N.V. confirms that the product AMOXY-KEL 15% (100ml) 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 AMOXY-KEL 15% (100ml) has been manufactured according to the formula of AMOXY-KEL 15% which has been registered in Romania.

KELA N.V.



Sint Lenaartseweg 48
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Belgium