

CERTIFICATE OF CONFORMITY / QUALITY

Date: 06/12/2021

AMOXY-KEL 15% 100 ML – batch 4012136 – exp. 06-2024

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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ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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LIBERTATII STR. 13
420155 BISTRITA (JUD. BISTRITA-NASAUD)
ROMANIA

Hoogstraten, 07.12.2021

ORIGINAL**Material**

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

Pharmaceutical Form:

Sterile suspension

Batch 4012136 / Manufacturing Date 06.2021 Expiry date 06.2024

Inspection lot 40000062792 from 11.2021

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)	%	101	98	102
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	%	98,1	95,0	105,0
Assay: Butylhydroxytoluene	%	99,0	90,0	110,0
Sterility		Complies		