

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 06.05.2022

ORIGINAL**Material**

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

Pharmaceutical Form:

Sterile suspension

Batch 4013155 / Manufacturing Date 06.2021 Expiry date 06.2024

Inspection lot 40000065171 from 03.2022

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		