

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 29.11.2

ORIGINAL

Material
C614100-001079-01 AMOXY-KEL 15% 100 ML
Pharmaceutical Form:
Sterile suspension
Batch 4017482 / Manufacturing Date 10.2023 Expiry date 10.2026

Inspection lot 40000074358 from 10.2023

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 excipiens q.s.ad 1 ml

Aspect: white to pale yellow suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (100 ml) (NLT)	%	101	100	
Resuspendability	ROT	10		20
Relative density		0,983	0,950	1,000
Viscosity	mPa.s	55	20	200
Id: Amoxicillin trihydrate		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Amoxicillin	%	99,5	95,0	105,0
Assay: Butylhydroxytoluene	%	99,7	90,0	110,0
Sterility		Complies		