

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 08.03.2024

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4017823 / Manufacturing Date 02.2024 Expiry date 02.2027

Inspection lot 40000075783 from 02.2024

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)	%	102	100	
Resuspendability	ROT	18		20
Relative density		0,982	0,950	1,000
Viscosity	mPa.s	55	20	200
Id: Amoxicillin trihydrate		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Amoxicillin	%	99,4	95,0	105,0
Assay: Butylhydroxytoluene	%	100,9	90,0	110,0
Sterility		Complies		