

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 23.04.2025

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4020408 / Manufacturing Date 08.2024 Expiry date 08.2027

Inspection lot 40000080819 from 02.2025

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) (NLT)	%	101	100	
Resuspendability	ROT	4		20
Relative density		0,983	0,950	1,000
Viscosity	mPa.s	54	20	200
Id: Amoxicillin trihydrate		Complies		
Id: Butylhydroxytoluene		Complies		
Assay: Amoxicillin	%	99,7	95,0	105,0
Assay: Butylhydroxytoluene	%	99,4	90,0	110,0
Sterility		Complies		