

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 27.11.2024

ORIGINAL**Material**

L349251-001079-01 KELAMOXIL LA 150 MG/ML 250 ML (PET)

Pharmaceutical Form:

Sterile suspension

Batch 4019832 / Manufacturing Date 08.2024 Expiry date 08.2026

Inspection lot 40000079286 from 10.2024

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 equivalent with 150 mg Amoxicillin - excipients q.s ad 1 ml

Aspect: white to greyish-white suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Extractable volume (250 ml) (N	%	102	100	
Relative density		0,985	0,950	1,050
Particle size: x90	µm	9		15
Resuspendability		Complies		
Id: Amoxicillin trihydrate: RT		Complies		
Id: Amoxicillin trihydrate: UV		Complies		
Assay: Amoxicillin	%	97,8	95,0	105,0
Sterility		Complies		
Rls: sum penicilloic acids	%	0,4		2,0
Rls: sum penilloic acids	%	< 0,3		2,0
Rls: any other imp	%	0,6		1,0
Rls: sum of imp	%	0,6		3,0