

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 12.01.2024

ORIGINAL

Material

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

Pharmaceutical Form:

Sterile suspension

Batch 4017606 / Manufacturing Date 10.2023 Expiry date 10.2025

Inspection lot 40000074912 from 11.2023

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 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	%	101	100	
Relative density		0,987	0,950	1,050
Particle size: x90	µm	9		15
Resuspendability		Complies		
Id: Amoxicillin trihydrate: RT		Complies		
Id: Amoxicillin trihydrate: UV		Complies		
Assay: Amoxicillin	%	98,2	95,0	105,0
Sterility		Complies		
Rls: sum penicilloic acids	%	< 0,3		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