

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****L349101-001079-01 KELAMOXIL LA 150 MG/ML 100 ML (PET)****Pharmaceutical Form:****Sterile suspension****Batch 4017605 / Manufacturing Date 10.2023 Expiry date 10.2025****Inspection lot 40000075009 from 12.2023****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 (100 ml) (N	%	102	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