



KELA N.V.
St-Lenaartseweg 48
B-2320 Hoogstraten
Belgium

T. +32 3 340 04 11
F. +32 3 340 04 23
E-mail: info@kela.be
BTW BE 0403.835.645
RPR Turnhout

SOP 426
Page 1/ 1

ANALYSE CERTIFICAAT - CERTIFICAT D'ANALYSE - CERTIFICATE OF ANALYSIS

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

Hoogstraten, 29.11.2018

ORIGINAL

Material

C612999-001079-01 ALBENDAKEL 10% 1 L

Pharmaceutical Form:

Non sterile suspension

Batch 4003194 / Manufacturing Date 10.2018 Expiry date 10.2020

Inspection lot 40000038901 from 10.2018

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: Albendazolum 100 mg - excipients q.s.ad 1 ml

Aspect: white to grey-white suspension

Characteristic	Unit	Value	Lower Limit	Upper Limit
Aspect		Complies		
Average volume (1000 ml)	%	99,35	98,00	102,00
pH		6,34	5,50	7,50
Relative density		1,053	1,045	1,060
Viscosity	mPa.s	896	100	1500
Id: Albendazole		Complies		
Assay: Albendazole	%	101,96	95,00	105,00

KELA N.V.
SINT LENAARTSEWEG 48
2320 HOOGSTRATEN
BELGIUM

Dig. Sign.: Van Buggenhout Kris
28.11.2018 14:31:46

Qualified Person

Conclusion:
Quality test complied