



CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Page 1/2

Product name: BIOMECTIN 1% 50ML HU Manufacturing date: 03/03/2018
 Batch number: 6B0731E Expiration date: 03/03/2019

TESTS	SPECIFICATIONS	RESULTS
Product appearance	Clear, colorless solution	Pass
Content in unit container 50ml	>= 50 <= 55 ml	51 ml
Relative density	>= 1.080 <= 1.200 g/ml	1.109 g/ml
Viscosity in 20°C	>= 25 <= 35 cP	29 cP
Identification Ivermectin		
TLC method	Confirm with Rf	Pass
Spectrophotometric method	Confirm with spectrum	Pass
HPLC method	Confirm with RT	Pass
Identification Glycerol formal		
TLC method	Confirm with Rf	Pass
GC method	Confirm with RT	Pass
Identification Propylene glycol		
TLC method	Confirm with Rf	Pass
GC method	Confirm with RT	Pass
H2B1a compound assay	>= 90 % m/v	98 % m/v
Assay Ivermectin		
Total of H2B1a and H2B1b	>= 0.55 <= 1.05 % m/v	0.88 % m/v
Propylene glycol assay	>= 54 <= 66 % m/v	68 % m/v
Glycerol formal assay	>= 38 <= 44 % m/v	40 % m/v

This document has been produced electronically and is valid without a signature

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Sąd Rejonowy w Zielonej Górze VIII Wydział Gospodarczy KRŚ o numerze 8060044225 Wysokość kapitału zakładowego 3 500.000 Zł



CERTIFICATE OF ANALYSIS

Page 2/2

FINISHED PRODUCT		
Product name : BIOMECTIN 1% 50ML HU	Manufacturing date :	03/03/2016
Batch number : 6B0731E	Expiration date :	03/03/2018
TESTS	SPECIFICATIONS	RESULTS
HPLC purity		
Impurities of RRT 1,3-1,5	<= 2.5 %	
Any other impurity	<= 1 %	1.8 %
Total	<= 5 %	0 %
		3 %
Sterility	Sterile	Pass

I hereby certify that this lot is manufactured, packed and labelled under conditions as stated in current European Union rules for Good Manufacturing Practice, for medicinal products for veterinary use, and the finish product in all aspects meets marketing authorization requirements

Approved by QC: Przemysław KOWALSKI

Date: 29/03/2016 15:33:35

Released by Qualified Person

Date: 12/07/2016 11:01:55

Decision: FULL RELEASE

Not tested - According to the requirements of the marketing authorization the parameter is not tested routinely

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Meoszám:160800019/07/T

3.pld. Kiadva: 16/08/17

Min.biz.: