

Biomectin 1% injekció (HU) A.U.V.
Gysz:6B3531B Lej:19/10/12
Kisz:50ml Me.:darab
DR. SZÉKELY KFT. részére

2151 Fót
Keleti Márton u. 19.
Tel:27/537-100
Fax:27/537-100



BATCH CERTIFICATE FOR MEDICINAL PRODUCT

Name, strength/potency, dosage form	Biomectin 1%, 10mg/ml, solution for injection
Package size	50 ml
Batch number of the finished product	6B3531B /
Name of the destination country / countries of the batch	Hungary
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 [when within the EU] with the requirements of the Marketing Authorisation(s) of the destination country/countries.	
Name of the Qualified Person certifying the batch	Mariola Kiszewska
Signature of Qualified Person certifying the batch	
Date of signature	2016-11-28

Vetoquinol Biowet Sp. z o.o.
Adres: ul. Kos Gdynskich 13-14, PL-66-400 GORZÓW WLKP.
tel.: +48/95/ 728 55 00 + 01, fax: +48/95/ 735 90 43
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e-mail: info.pl@vetoquinol.com www.vetoquinol.pl
Sąd Rejonowy w Zielonej Górze VIII: Wydział Gospodarczy KRS o numerze 000064225

Bank: Bank GZ BNP Paribas S.A.
EUR PL79 1400 1084 0004 0000 0000 0000 0000 0000 0000 0000 0000
USD PL52 1400 1084 0004 0000 0000 0000 0000 0000 0000 0000 0000
CHF PL25 1400 1084 0004 0000 0000 0000 0000 0000 0000 0000 0000
PL 37 1400 1084 0004 0000 0000 0000 0000 0000 0000 0000 0000
REGON 219527474 NIP 592 11 138 007
Wysokość kapitału zakładowego: 11 000 000 zł

PHOENIX Pharma Zrt.
Fóti Telephely
2151 Fót, Keleti Márton út 19.
..... sz. másolati példány
Csak a piros szín hiteles!
20-03



CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT		
Product name : BIDMECTIN 1% 50ML HU	Manufacturing date : 12/10/2016 /	
Batch number : 6B3531B /	Expiration date : 12/10/2019 /	
TESTS	SPECIFICATIONS	RESULTS
Product appearance	Clear, colorless solution	Pass
Content in unit container 50ml	$\geq 50 \leq 55$ ml	51 ml
Relative density	$\geq 1,080 \leq 1,200$ g/ml	1,109 g/ml
Viscosity in 20°C	$\geq 25 \leq 35$ cP	28 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	97 % m/v
Assay Ivermectin		
Total of H2B1a and H2B1b	$\geq 0,95 \leq 1,05$ % m/v	1,00 % m/v
Propylene glycol assay	$\geq 34 \leq 66$ % m/v	58 % m/v
Glycerol formal assay	$\geq 36 \leq 44$ % m/v	41 % m/v

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Vetoquinol Biowet Sp. z o.o.
 Adres: ul. Kas. Gójskich 13-14,
 Tel. +48/95/728 55 00 -1,
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 Sąd: Rejonowy w Zielonej Górze VIII wydział Gospodarczy KRS o numerze 000064225 Wysokość kapitału zakładowego 3 500 000 zł

PL- 64-400 GORZÓW WLKP
 e-mail: info@vetoquinol.com
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 NIP 599-01-08-560

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CERTIFICATE OF ANALYSIS

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FINISHED PRODUCT

Product name : BIOMECTIN 1% 50ML HU	Manufacturing date : 12/10/2016
Batch number : 6B3531B	Expiration date : 12/10/2019

TESTS	SPECIFICATIONS	RESULTS
HPLC purity		
Impurities of RRT 1,3-1,5	<= 2.5 %	1.8 %
Any other impurity	<= 1 %	0 %
Total	<= 5 %	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 Q/C : Przemyslaw KOWALSKI	Released by Qualified Person : Mariola KISZEWSKA
Date : 25/11/2016 16:11:01	Date : 28/11/2016 14:16:48
	Decision : FULL RELEASE

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

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Vetoquinol Biowet Sp. z o.o.

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Te: +48/95/728 55 00 i.t.

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Sąd Rejonowy w Zielonej Górze VIII wdział Gospodarczy KRS o numerze 000066225. Wysokość kapitału zakładowego: 3 500 000 zł

Pl - 66-400 DORZGW WLKP

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NIP 599-01-08-560

PHOENIX Pharma Zrt.

Fővárosi telephely

2151 Fővárosi Keleti Márton út 19.

Min. biz.

..... sz. másolat példány

Csak a piros szín hiteles!

20-03

Meoszám:161200592/07/T

1.pld.

Kiadva: 18/11/26